From: Rabin, Tara G. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D6E14C0D07AD46CA812A39A72C751BFE-TARA.GOODIN]
Sent: 2/20/2022 11:22:35 AM
To: Newhart, Corinne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656a525a42e547959efea21ab442bcd6-Corinne.New]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Farrar, Jeff A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c862ce01b6714d4c9c5057306240469e-Jeff.Farrar]; Prater, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291b4eab842148baba96df3bd8c31058-DPRATER]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Ramos, Melissa * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30d58cc38d04aa3894a8de1d0113efb-Melissa.Ram]; Smith-Dulley, Jasmine * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa7cb8415b5a4e259866911bf4caed7d-Jasmine.Smi]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]; Rhodes, Courtney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=431fdf10c12843a9ac22981ad1d6d227-Courtney.Rh]
CC: Morris, Larry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591baaec2f0841a9b712b0c864bfc8f5-Larry.Morri]; Summers, Tracy S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d149bd080a243e2ae15ebdec8d15551-TSUMMERS]; Moxley, Shera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dbddbf813674d38ac4a43176e2398e4-Shera.Moxle]; CFSAN-OCD-CPES [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85ce6b6b5764222bd3060dcdd1f5976-CFSAN-OCD-C]; CFSANTradepress [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3786796db71b4899877e851ca8dcd9ce-CFSANTradep]; CFSANEXECSEC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=468d52748b974fa598d4dfb4a83ab38f-OFVM-CFSAN-]; OCA-OPLIA-Congressional-Government [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadd1dfbd5a648a186d6c00d81d6d0f3-OO-OFBA-Con]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Das, Sharmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebe21fc31d6d46cf8540275f6ff52c73-Samarpita.D]; Abi-Khattar, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a37f6065cf544cb91915274e0203d08-Cathy.Ghale]; CFSAN-Webmaster [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c802bd23bcf4276b81406b691b66ace-CFSAN-Webma]; Lehman, Kristen

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=094248c8546e40b898eae67f7f86fc94-Kristen.Leh]; Benton, Denise
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d254dc9aa5f543698fae327f4ab7552d-Denise.Bent]; Colonius, Tristan
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Lockeed, Matthew
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a2fe9a22e8f940fa8761fad18ef37dd0-Matthew.Loc]; Goitom, Mahlet
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3476ef7044d54ad88f0d8c8639fdc9d8-Mahlet.Goit]; Hattis, Daniel
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; Earley, Rosemary
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05737f759eb54e9188cb16cbbe467d12-Rosemary.Ea]; Vera, Rita
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d9b116472abd409995f72f68170a1f16-Rita.Vera]; Price, Deborah S
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6eae4da0f0634de3b9f5a200f4f356e5-DPRICE]; Iguina, Graciela
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2804fa3e24084090b2f572fc810817f0-GIGUINA]; ORA Press
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=18d78505a1a04d2ea01dce130f0d5de8-ORAPress]; Norris, Gary
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc19fae0c7d44332a71e1ff7aa2cefbc-Gary.Norris]; CFSAN OC SRT
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f8a10a0d30a646e5977d8316eeb0b822-CFSAN OC SR]; CFSANEXECSEC
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=468d52748b974fa598d4dfb4a83ab38f-OFVM-CFSAN-]; OC OCC Legal
Requests-Foods Mailbox [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9958fceea93b4dc1aea7b45e60b3225f-OCOCCLegalR]; Beckerman, Peter
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Alexander, Nicholas
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; CORE Senior Leadership
Team [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f9db20a6993a47d49e05807354ebc954-CORE Senior]; CORE Communications
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c135f0a423cf4631bab8155fda87edfc-CORE Commun]; Tobias, Lindsay
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; McDermott, Catherine
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=09adb790c3854fb7a4b11353b41ee618-Catherine.M]; Byerts, Kirsten
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d3d165c657f04e43bd053efb83e96459-Kirsten.Bye]; FDASocialMedia
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d22cede3bcd4b289b6aa1224c00495a-FDASocialMe]; OMA Foods Vet Med
Team [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c4666fd90ccf4a62a772b655706f7b3f-OMA Foods V]; OMA Leadership
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6bede136d65e4c20bd392c18351a87c2-OMA Leaders]; FDASocialMedia
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d22cede3bcd4b289b6aa1224c00495a-FDASocialMe]; CORE Response Team
2 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5645ad676ffa4838a7ae7ff39511b552-CORE Respon]; Lotze, Andrea
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e03cd80247c94486b9c4f4d1a0a9dfaf-Andrea.Lotz]; Assar, Carrie
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=473af4b8efca47f28f476c771ff32395-Carrie.Assa]; Kulas, Megan

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870ffe8f17ec4b4faa80d94743e2c6e3-Megan.Kulas]; Davis, Marjorie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b344bd7de4524250ada67247b7c251f1-Marjorie.Da]; Klontz, Karl C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f034aab9aa2d44d5ab4a6a036be0686b-KKLONTZ]; Pettengill, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=75c30e036b21489a94eff12e48d44daa-James.Pette]; Oxenham, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b682119aebb490b87abe0fc19b0c09d-Ann.Oxenham]; Hollis, Simone [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eea337712468aabb2f6923b1afe47-Simone.Edmo]; Newby, Edette J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2884e947b2394b3da6361941a43edb5e-ENEWBY]; Darlington, Leonora [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6df123a2cf37410ea4e42ae76b372145-Leonora.Dar]; Smoot, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbebf67a5fa842c2bd91085804b2a087-Leslie.Smoo]; Sheehan, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=768cb0855d5f4eedb2e8f999846ce0bd-JSheehan]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Fox, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76205251cf1349c19a87278dc8ce840c-TFOX]; Jasperse, Carie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9fe77657ab4444b9b27100a347228b2-Carolyn.Jas]; Singleton, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b70632897eee4a66a8e6bf7681210a85-Shannon.Chi]

Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Attachments: Infant Formula Recall 2.20.22.docx

Providing an update on additional media coverage since the Friday evening report. We continue to see key facts of the public advisory and recall highlighted, with occasional mentions of this warning coming amidst an ongoing infant formula supply-chain related shortage. **However, we are now started to see mentions of local recall-related supply issues.** To date, there have been four mentions of supply issues specifically related to the Abbott recall and FDA's related advisory in local news outlets: CBS Kansas local news points out the WIC customers were affected by the recall and quotes parents who had to throw away their WIC-purchased product as a result of the recall and noted trouble exchanging the formula as advised by Abbott, NBC Connecticut local news quotes a doctor at Connecticut Children's saying the hospitals supply is affected by the recall as well as a local diaper bank, and Fox News Connecticut notes parents having a difficult time finding infant formula amid supply shortages are now also dealing with a product recall. The Office of Media Affairs is continuing to closely monitor both for mentions on traditional and social media. Notable new media coverage:

- NBC nightly news ran a segment, "Nationwide baby formula recall causes panic for some parents," which included aspects related to how the recall, unique formulations, and supply-chain issues are affecting consumers and their families.

- NBC Connecticut's article notes recall-related supply issues at a local hospital. "According to Dr. Sink, the supply of formula at Connecticut Children's is affected. They are looking for alternatives. 'We are actively working through either liquid products that are ready to feed, those are not affected, or other products that were not part of the recall,' said Dr. Sink." The article also notes that The Diaper Bank of Connecticut is affected by the FDA's warning. They have several hundred cans of powdered infant formula that will now go to waste.

- FOX 61 Connecticut says parents having a difficult time finding infant formula amid supply shortages are now also dealing with a product recall.

- ABC Wichita, Kansas (KAKE)'s points out that many parents get their formula under the WIC program and all their stock was impacted by the recall. The recall affects Similac, Alimentum and EleCare products with an expiration date of April 1, 2022 or later. Kenny Geiger gets Similac formula for his son through the Women, Infant and Children, or WIC, program. "'There's a lot of people that, you know, get all their cans on WIC, and all of their cans were recalled,' Geiger said. Geiger said it was a close call when he and his wife found out about the recall. 'We had to dump out...cause we make our pitchers the night before for the whole next day...so we had to dump that whole thing out,' he said. Only three of his cans were a part of the recall. He said he feels lucky that he has enough product to get by for now, but he knows that's not the case for others. 'There's a lot of people who get it on WIC and a lot of people that can't afford to just go around and buy one, two, three, five more cans of formula to get through the month'...' Geiger said he has also had a hard time exchanging the formula. However, according to Abbott, the manufacturer's, website, you can apply for a refund or replacement online by clicking here.'"
- Pittsburgh Action News 4 discussed a local infant who is hospitalized this week after using the recalled infant formula. "Edward Savka's 10-month-old daughter is being treated at UPMC Children's Hospital. Savka said he's concerned she got sick from a baby formula that is now on recall. Savka showed Pittsburgh's Action News 4 the bottle of Similac powdered baby formula that he and his wife opened Wednesday evening to give their daughter. A few hours after that, Savka said the family was at UPMC Children's Hospital. He said his daughter had a fever, a seizure and other symptoms."
- The New York Times highlighted that the recall, which comes during a drastic baby food shortage, affects certain lots of Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later. Products affected by the recall will also have a long sequence of numbers on the bottom of the container that starts with the first two digits 22 through 37, and contains K8, SH or Z2.

U.S. Media Coverage Update, 2/20/22

Nationwide baby formula recall causes panic for some parents
Date: Published, February 18, 2022
NBC nightly news included aspects related to how the recall, unique formulations, and supply-chain issues are affecting consumers and their families.

###

FDA Issues Warning Against Using Certain Powdered Baby Formulas
The Diaper Bank of Connecticut is affected by the FDA's warning. They have several hundred cans of powdered infant formula that will now go to waste.
By: Siobhan McGirl
Date: February 18, 2022
NBC Connecticut

The U.S. Food and Drug Administration is warning consumers against using certain powdered baby formulas that have been linked to serious infections in infants.

According to an advisory, the FDA is investigation four consumer complaints of "infant illness related to products from Abbott Nutrition's Sturgis, MI facility received from 9/20/2021 to 1/11/2022."

Abbott Nutrition issued a voluntary recall of some of their products. The FDA's investigation includes four infant illnesses in three states. No illnesses connected to the formula have been identified in Connecticut.

According to a news release, the FDA is advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas if:

- the first two digits of the code are 22 through 37; and

- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.

You can also check to see if your formula is impacted by clicking here.

According to Dr. Sink, the supply of formula at Connecticut Children's is affected. They are looking for alternatives.

"We are actively working through either liquid products that are ready to feed, those are not affected, or other products that were not part of the recall," said Dr. Sink.

If your formula is affected, Dr. Sink said it's best to look for another option as well.

"That may mean buying another can or that may mean talking to your pediatrician to find out what alternatives there may be for your particular baby," said Dr. Sink.

According to the FDA, parents and caregivers should never dilute infant formula and should not make or feed homemade infant formula to infants.

The Diaper Bank of Connecticut has several hundred cans of powdered baby formula that will now go to waste. The cans were intended for families in need, but the nonprofit learned Friday that they were impacted by the recall.

"Disappointment and concern for the families that we serve," said Janet Stolfi Alfano, the executive director of the Diaper Bank.

Her team is still waiting to hear if they will get replacements for the formula. In the meantime, they are asking anyone who received formula from them to check the can.

"Because we want to make sure that the families are safe," said Stolfi Alfano.

The FDA advisory does not include liquid formula products or any metabolic deficiency nutrition formulas.

# # #

FDA warns against using certain powdered baby formulas, Pittsburgh family says their child is now sick

"She had all the symptoms of food poisoning. Severe diarrhea, obviously they're checking for COVID, can't rule that factor out but I don't think it's COVID," Edward Savka said.

By: Staff
Date: February 18, 2022
Pittsburgh Action News 4

U.S. health officials warned parents on Thursday not to use three popular powdered infant formulas manufactured at an Abbott plant in Michigan that investigators recently linked to bacterial contamination.

A Frazier Township family told Pittsburgh's Action News 4 Friday that they believe their child may have gotten sick because of it.

Edward Savka's 10-month-old daughter is being treated at UPMC Children's Hospital. Savka said he's concerned she got sick from a baby formula that is now on recall.

Savka showed Pittsburgh's Action News 4 the bottle of Similac powdered baby formula that he and his wife opened Wednesday evening to give their daughter.

"She actually had the bottle before she went to bed around 7:30. The next morning I'd say around 9 a.m. she started spiking a fever and by 1 p.m. she was at her PCP," Savka said.

A few hours after that, Savka said the family was at UPMC Children's Hospital. He said his daughter had a fever, a seizure and other symptoms.

"She had all the symptoms of food poisoning. Severe diarrhea, obviously they're checking for COVID, can't rule that factor out but I don't think it's COVID," Savka said.

The Food and Drug Administration announced the recall on Thursday for certain powdered baby formulas, including Similac.

Savka said his wife found out about the recall and immediately checked to find it was a match.

According to the FDA, there have been four known instances of the formula being linked to bacterial infections and it may have contributed to one death.

Savka said doctors are testing now to confirm a potential link between the formula and his daughter's illness. He said she's never had health issues before and now he just wants people to be aware.

"The first thing that came to mind was to make sure my daughter is OK first then I messaged a few of my friends that also have infant sons and daughters to check their bottle, but like I said very surprised," Savka said.

These cases are all linked to a manufacturing facility in Michigan.

# # #

Some Wichita parents worried and frustrated about baby formula after nationwide recall

By: Maeve Ashbrook
Date: February 19, 2022
ABC Wichita, Kansas (KAKE)
Some Wichita parents are worried after a nationwide recall of powdered baby formula.

The recall affects Similac, Alimentum and EleCare products with an expiration date of April 1, 2022 or later. Kenny Geiger gets Similac formula for his son through the Women, Infant and Children, or WIC, program.

Baby formula recall affects lots of Similac, Alimentum and EleCare

"There's a lot of people that, you know, get all their cans on WIC, and all of their cans were recalled," Geiger said.

Geiger said it was a close call when he and his wife found out about the recall.

"We had to dump out…cause we make our pitchers the night before for the whole next day…so we had to dump that whole thing out," he said.

Only three of his cans were a part of the recall. He said he feels lucky that he has enough product to get by for now, but he knows that's not the case for others.

"There's a lot of people who get it on WIC and a lot of people that can't afford to just go around and buy one, two, three, five more cans of formula to get through the month."

Jasmine Bird, a mother of five, is one of those parents. She's worried about finding safe formula for her daughter.

To get through this weekend, she had to get formula from the hospital.

"They had to give me some, because I didn't have anything for the night," Bird said. "But, they didn't really give me that much, but it helped."

Bird found out the cans she had at her house were effected by checking online. You can do the same by clicking here.

Geiger said he has also had a hard time exchanging the formula. However, according to Abbott, the manufacturer's, website, you can apply for a refund or replacement online by clicking here.

###

Formula recall adds stress for Conn. parents already dealing with shortages

Three popular infant formulas have been recalled, which may further impact supply and demand issues that have made formulas hard to find.

By: Gaby Molina
Date: February 18, 2022
FOX 61 Connecticut

Parents having a difficult time finding infant formula amid supply shortages are now also dealing with a product recall.
"It is very scary cause you can't feed your own child," said Kelly Noble of Ansonia.

She said she spends hours every day trying to track down the formula she needs to feed her 11-month-old daughter.

"That's how crazy you are. You literally do nothing but, like, search. I check Target's stock probably every day, morning and night," Noble said. "We've called maybe eight stores today, we found it at one store, they have three bottles. One bottle gets me one day."

She started noticing the effects of supply chain issues about two months ago when it suddenly became very difficult to find baby formula.

"You're very panicked every day because you're scared you're going to run out," Noble said.

She said she's not alone though. Mom groups she's a part of on Facebook show parents around the country are dealing with the same issues.

Adding to the stress, the Food and Drug Administration (FDA) is now warning parents not to use three popular formulas because of possible bacterial contamination.

Abbott has recalled certain lots of Similac, Alimentum, and Elecare. The products have a number on the bottom of the container with the first two digits "22 through 37, contains K8, SH, or Z2 and with an expiration date of April 1, 2022, or after," according to the company.

The FDA is investigating four reports of infants who were hospitalized after using the formula. One of those infants died.

"The likelihood of this happening is relatively low likelihood," said Dr. David Sink, a neonatologist at Connecticut Children's. "If you see that your baby is acting differently if you see that your baby is not feeling well, is having a fever, or just not very active then you should call your pediatrician right away."
Health officials said parents should stop using the formula and seek out other options for their baby.

"Consult with your healthcare provider or pediatrician because they can advise you on the alternative formula that you should use at this time," said Laurence Burnsed, director of health and social services for the town of East Hartford.

# # #

Recall affects Similac, Alimentum and EleCare formulas made at Abbott's Sturgis, Mich., plant; FDA is investigating complaints of four infant illnesses3 Types of Baby Formula Recalled After Reported Bacterial Infections

Abbott Nutrition issued voluntary recalls of their popular Similac, Alimentum and EleCare formulas after four infants were hospitalized with bacterial infections.

By: Isabella Grullón Paz
Date: February 18, 2022
The New York Times

Abbott Nutrition, a popular baby food manufacturer, announced on Thursday that it was voluntarily recalling three types of infant formula after four babies became sick with bacterial infections after consuming the products.

The recall includes select lots of Similac, Alimentum and EleCare formulas that were manufactured at an Abbott facility in Sturgis, Mich. It comes after the Food and Drug Administration received four consumer complaints of bacterial infections related to the formulas.

Three of the complaints concerned Cronobacter sakazakii, a bacterium that can cause severe, life-threatening infections or inflammation of the membranes that protect the brain and spine. Cronobacter infection may also cause bowel damage and may spread through the blood to other parts of the body, according to the F.D.A.

The F.D.A. had posted a recommendation on Thursday to parents warning them about the products after illnesses in Minnesota, Ohio and Texas resulted in the hospitalization of four infants. The bacterium may have contributed to a death in one case, the agency said.

"We value the trust parents place in us for high quality and safe nutrition and we'll do whatever it takes to keep that trust and resolve this situation," Vicky Assardo, the senior director of global public affairs at Abbott Nutrition, said in a statement on Friday night.

The recall, which comes during a drastic baby food shortage, affects certain lots of Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later. Products affected by the recall will also have a long sequence of numbers on the bottom of the container that starts with the first two digits 22 through 37, and contains K8, SH or Z2.

The recall does not apply to Abbott products manufactured in other facilities, the company said.

In its announcement, Abbott did not specify how many units the recall affected, but Similac baby formulas are highly popular in the United States and abroad.

In its statement announcing the recall, Abbott said that it conducts "routine testing for Cronobacter sakazakii and other pathogens."

In tests of the Sturgis facility, the company said, it "found evidence of Cronobacter sakazakii in the plant in non-product contact areas," but no evidence of Salmonella Newport, the bacterium cited in the fourth consumer complaint.

"No distributed product has tested positive for the presence of either of these bacteria," Abbott said.

But the F.D.A. said it had initiated an on-site inspection of the plant in which environmental samples tested positive for Cronobacter. Inspectors have also uncovered potential manufacturing problems, and a review of internal records revealed the company's past destruction of product because of bacterial contamination, the agency said.

Frank Yiannas, the F.D.A. deputy commissioner for food policy and response, said he was "deeply concerned" about the reports, since formula is a "product used as the sole source of nutrition for many of our nation's newborns and infants."

The F.D.A. is working with the Centers for Disease Control and Prevention along with federal and local authorities in Minnesota, Ohio and Texas in its investigation.

The F.D.A. recommends that parents and caregivers of infants who have used the recalled products contact their child's health care provider if they are concerned about the health of their child.

###

Baby Formula Recalled by Abbott After Reports of Bacterial Contamination

By: Omar Abdel-Baqui
Date: February 18, 2022
The Wall Street Journal

Abbott Laboratories ABT -3.14% said it is recalling three types of baby formula after consumer complaints of bacteria contamination that could cause severe illness in infants.

The Food and Drug Administration is investigating complaints of four infant illnesses in Minnesota, Ohio and Texas related to cronobacter and salmonella contamination. All four infants were hospitalized and one died. Cronobacter may have contributed to that death, the agency said.

Cronobacter illnesses, which include sepsis and meningitis, are rare but can be lethal for infants, according to the Centers for Disease Control and Prevention. Salmonella can cause fever and digestive issues, and sometimes severe illness, according to the CDC.

Abbott said Thursday it was voluntarily recalling its Similac, Alimentum and EleCare formulas manufactured in its Sturgis, Mich., plant and with an expiration of April 1 or later. The recall doesn't include any metabolic deficiency nutrition formulas, the company said. The FDA said the Abbott facility in Sturgis isn't producing or distributing product at this time.

An Abbott spokeswoman said the company will address the scope of the recall at a later date. She added that the four complaints came between September 2021 and January.

The FDA began an inspection of the Sturgis plant on Jan. 31, and said cronobacter was present in environmental samples. Abbott's internal records indicated environmental contamination with cronobacter and that the company had destroyed product due to its presence, an FDA review found.

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," Frank Yiannas, FDA deputy commissioner for food policy and response, said in a statement Thursday. "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products."

Abbott said that it tests for pathogens including cronobacter and salmonella before releasing its products. The company said none of its distributed product tested positive for the presence of either bacteria thus far, and that more testing is ongoing. The recalled products were distributed across several states and to countries outside the U.S.

"We know parents depend on us to provide them with the highest quality nutrition formulas," said Joe Manning, executive vice president of nutritional products at Abbott. "We're taking this action so parents know they can trust us to meet our high standards, as well as theirs."

The CDC says powdered infant formula can't be sterilized. Bacteria could get into formula powder if contaminated raw materials were used to make the formula, or if the formula touched a contaminated surface during the manufacturing process. It could also become contaminated at home, the CDC says.

The products under recall have a multidigit code in which the first two digits are 22 through 37, the code contains K8, SH or Z2, and the expiration date is April 1 or later.

Consumers can call +1-800-986-8540 or visit similacrecall.com to find out if their product is included in the recall.

###

FDA urgently warns against using these baby formulas made in the same Michigan plant after infant dies and three fall ill

By: Andrea Cavallier for Dailymail.com and Associated Press
Date: Published, February 18, 2022; Updated, February 19, 2022
The Daily Mail

- **Three types of baby formula made in the same Michigan plant were recalled**
- **The FDA says four babies were hospitalized, and one of them died, after consuming the formula**
- **The formulas recalled are Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later**
- **All are Abbott Nutrition's Sturgis products made in a factory in Michigan**
- **The product was distributed throughout the US and overseas**
- **Abbott said parents can identify the recalled products by examining the number on the bottom of each container**
- **The affected formulas have a number starting with 22 through 37, contain K8, SH or Z2 and have an expiration date of April 1, 2022, or later**
- **Parents can type in the code on the bottom of the package at similacrecall.com to see whether their product is affected or call 800-986-8540**
- **Inspectors have also uncovered potential manufacturing problems, and past records showing the destruction of formula due to bacterial contamination**
- **Abbott could not specify how many units the recall includes**

U.S. health officials urgently warned parents Thursday against using three popular baby formulas, manufactured at an Abbott plant in **Michigan**, that investigators recently linked to bacterial contamination after an infant died and three others fell ill.

The Food and Drug Administration (FDA) said it is investigating four reports of infants who were hospitalized after consuming the formula, including one who died.
The agency said one of the cases involved salmonella and three involved Cronobacter sakazakiim, a rare but dangerous germ that can cause blood infections and other serious complications.

On Thursday, the FDA said buyers should avoid Similac, Alimentum and EleCare formulas if they meet all of the following criteria: the first two digits of the code are 22 through 37; the code on the container includes K8, SH or Z2; and the expiration date is 4-1-2022 (APR 2022) or later.

Abbott said parents can identify the recalled products by examining the number on the bottom of each container.

The affected formulas have a number starting with 22 through 37, contain K8, SH, or Z2 and have an expiration date of April 1, 2022 or later.

Parents can also type in the code on the bottom of the package at similacrecall.com to see whether their product is affected or call 800-986-8540.

Abbott, one of the country's largest infant formula makers, said it is recalling all potentially affected products manufactured at the facility.

The recall affects certain lots of Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later. The product was distributed throughout the U.S. and overseas, the company said in a statement.

FDA staff are now inspecting Abbott's plant in Sturgis, Michigan, where environmental samples tested positive for the Cronobacter bacteria.

Inspectors have also uncovered potential manufacturing problems, and past records showing the destruction of formula due to bacterial contamination.

'We're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible,' said FDA Deputy Commissioner Frank Yiannas.

The FDA said it is working with federal and local authorities in Minnesota, Ohio and Texas- the states where the infant infections were reported.

Abbott could not specify how many units the recall includes, but brands like Similac are among the best-selling formulas in the U.S. and overseas.

'We value the trust parents place in us for high quality and safe nutrition and we'll do whatever it takes to keep that trust and resolve this situation,' a company spokeswoman said in a statement.

Abbott said parents can identify the recalled products by examining the number on the bottom of each container.

The affected formulas have a number starting with 22 through 37, contain K8, SH, or Z2 and have an expiration date of April 1, 2022 or later.

The company has also setup a website where parents can check if their products have been recalled.
The company said its own testing of finished product didn't detect any contamination. The recall does not affect liquid infant formulas or any other Abbott products.

# # #

FDA investigates possible Salmonella infections from powdered infant formula
By: Douglas Jones

Date: Posted February 17, 2022; Updated February 18, 2022
WFTS Tampa Bay ABC Action News

The U.S. Food and Drug Administration said on Thursday that the health agency is investigating multiple reported cases of Cronobacter and Salmonella infections that have been reported. Officials say all of the reported cases came after powdered infant formula was consumed.

The formula came from Abbot Nutrition's Sturgis, Minnesota facility, the FDA said in a statement. The agency is advising consumers to stop using certain powdered formula products from the brands Similac, Alimentum and EleCare.

Consumers are advised to look out for the following numbers in product codes on the packaging to determine which products in their homes to throw away, the FDA said:

- the first two digits of the code are 22 through 37; and
- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.

If you're unsure if your formula is involved in Abbott's voluntary recall, you can check your product's lot number on **Abbott's website here**.

There have been four illnesses so far, three of those were Cronobacter infections and one of them was Salmonella. According to the FDA, Cronobacter may have contributed to a death in one case.

States, where people were infected, include Minnesota, Ohio and Texas.

The FDA says their investigation is still ongoing and the company is working with the health agency to voluntarily recall the products in question.

Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response said in a statement, "As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections."

Yiannas said, "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible."

Cronobacter bacteria can cause severe, life-threatening infections and Salmonella bacteria can cause gastrointestinal illness and fever and can sometimes be fatal.

If you have any of the products contained in the voluntary recall you are advised to throw them away or take them back in a plastic bag to the point of sale for a refund.

# # #

FDA warns against using 3 powdered baby formulas linked to infections

By: Bob D'Angelo
Date: February 18, 2022
WSB-TV Atlanta 2 (Cox Media Group)

WASHINGTON — Health officials in the U.S. on Thursday warned parents not to use three powdered infant formulas manufactured at a plant in Michigan, as they were recently linked to bacterial infections.

The recall affects certain lots of Similac, Alimentum and EleCare, the FDA stated in a news release Thursday.

In the news release, the Food and Drug Administration said it was investigating complaints of Cronobacter sakazakii and salmonella Newport infections. All four of the cases came from powdered formula produced at Abbott Nutrition's Sturgis, Michigan, facility. Three of the cases involved Cronobacter sakazakii, a rare but dangerous germ that can cause blood infections, The Associated Press reported. The other case involved salmonella Newport, the FDA said.

The FDA said the cases were reported in Minnesota, Ohio and Texas, adding that Cronobacter may have contributed to a death in one case. All four cases sent victims to the hospital, the agency said.

Abbott said it was working with the FDA to initiate a voluntary recall of the affected products.

The affected products have an expiration date of April 1, 2022, or later, the FDA said. The product was distributed across the U.S. and overseas, the AP reported.

The FDA said it is advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas if:

- The first two digits of the code are 22 through 37; and
- The code on the container contains K8, SH or Z2; and
- The expiration date is 4-1-2022 (APR 2022) or later.

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," Frank Yiannas, FDA deputy commissioner for food policy and response, said in a statement. "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible."

Similac has set up a website where parents can check to see if their products have been recalled: https://www.similacrecall.com/us/en/home.html.

# # #

Indiana Department of Health: FDA warns consumers not to use certain powdered infant formula

By: Staff
Date: February 19, 2022
WIMS Radio

The Indiana Department of Health is sharing the information that the FDA is investigating consumer complaints of Cronobacter and Salmonella infections.

All of the cases are reported to have consumed powdered infant formula produced from Abbott Nutrition's Sturgis, MI facility.

Products made here can be found across the U.S. A link with more information can be found on the FDA's website.

# # #

FDA warns against using certain infant formulas over Salmonella risks

By: Staff
Date: February 18, 2022
Spectrum News

The Federal Drug Administration is investigating some brands of powdered infant formula produced from Abbott Nutrition's Sturgis, Michigan facility, after complaints of Salmonella and Cronobacter — which can cause diarrhea and urinary tract infections, and sometimes lead to deadly illness.

The FDA is advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas, which are sold around the country, if:

- the first two digits of the code are 22 through 37; and
- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.

Officials said four infants have been hospitalized in connection with the investigation, and "Cronobacter may have contributed to a death in one case," according to the FDA release.

The firm is working with the FDA to initiate a voluntary recall of potentially affected products.

What You Need To Know

- **FDA warns parents not to use Similac, Alimentum, EleCare powdered formulas**
- **FDA is investigating possible Salmonella and Cronobacter contamination at Abbott Nurtition's Sturgis, Michigan facility**
- **Products sold across the country with an expiration date of April 1, 2022 should not be used**
- **Four infants have been hospitalized in connection with the investigation and possibly one death**

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," said Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response. "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible."

Parents and caregivers of infants who have used these products, and are concerned about the health of their child, should contact their child's health care provider.

Symptoms of Salmonella and Cronobacter to look out for may include poor feeding, irritability, temperature changes, jaundice, grunting breaths, high fever, diarrhea, abdominal cramps, lethargy, rash, or blood in the urine or stool.

The FDA is continuing to investigate and will provide additional consumer safety information when it becomes available.

Products that do not contain the information listed above are not affected. The FDA advisory does not include liquid formula products or any metabolic deficiency nutrition formulas. Consumers should continue to use all products not covered by the advisory.

# # #

FDA Warns of Infant Formula Powders Tied to Infections

By: Robert Preidt
Date: February 18, 2022
InsideNova.com (Healthday News)

Several powdered infant formula products have been recalled by Abbott Inc., following reports of four infants developing bacterial infections after consuming the products, the U.S. Food and Drug Administration said Thursday.

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response, said in an agency news release. "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products... while we work to resolve this safety concern as quickly as possible."

Consumers should not use Similac, Alimentum, or EleCare powdered infant formulas if: the first two digits of the code are 22 through 37; the code on the container contains K8, SH or Z2; and the expiration date is 4-1-2022 (APR 2022) or later, the FDA warned.

The agency is investigating three *Cronobacter sakazakii* infections and one Salmonella Newport infection among four infants in three states — Minnesota, Ohio and Texas. All of the infants were hospitalized and *Cronobacter* may have contributed to a death in one case.

The recalled powdered infant formula products were produced at Abbott Nutrition's facility in Sturgis, Mich., and sold across the United States and likely exported to other countries, according to the FDA.

The agency said it has launched an inspection at the facility. To date, several environmental samples taken at the plant have tested positive for *Cronobacter*.

A review of Abbott's internal records also reveal environmental contamination with *Cronobacter* and the destruction of product due to the presence of *Cronobacter*, the FDA said.

The FDA is conducting the investigation with the U.S. Centers for Disease Control and Prevention and state and local agencies.

Cronobacter bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine).

Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths and abnormal movements, the FDA said.

Cronobacter infection may also cause bowel damage and may spread through the blood to other parts of the body.

If you have an infant who has consumed these products and you are concerned about their health, contact your child's health care provider. If your child is experiencing any of these symptoms, notify your child's health care provider and seek medical care for your child immediately, the FDA advised.

Salmonella can cause salmonellosis. Most people with salmonellosis develop diarrhea, fever and abdominal cramps. More severe cases of salmonellosis may include a high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and in some cases, may cause death, the agency said.

# # #

Tara G. Rabin
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-3157 / Cell: (b) (6)
Tara.Rabin@fda.hhs.gov

From: Rabin, Tara G.
Sent: Friday, February 18, 2022 7:40 PM
To: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pfaeffle, Veronika <Veronika.Pfaeffle@fda.hhs.gov>; Courtney Rhodes (Courtney.Rhodes@fda.hhs.gov) <Courtney.Rhodes@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox

<OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good evening – Attached and pasted below is an initial media coverage report following yesterday's announcement regarding Abbott infant formula. Coverage largely included the FDA's key messages about the public warning, product recall information, the agency's ongoing investigation efforts, as well as mention of the four infant illnesses (including one death) and hospitalizations in three states – Minnesota, Texas and Ohio. While The Today Show and CNN articles note issues related to infant formula supply chain-related shortages that have been ongoing, there are currently no mentions of hoarding or shortages reported related to the Abbott infant formula recall and FDA's related advisory. The Office of Media Affairs will continue to provide updates on coverage through the weekend, particularly monitoring both for any mentions of shortages specifically spurred by the Abbott recall and related FDA advisory.

Infant Formula Recall

U.S. Media Coverage, 2/18/22

Contents

Media Summary

On Thursday, February 17, 2022, the FDA released a press release with a quote from Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas while the agency investigates consumer complaints of Cronobacter sakazakii and Salmonella Newport infections.
Coverage largely included the FDA's key messages about the public warning, product recall information, the agency's ongoing investigation efforts, as well as mention of the four infant illnesses (including one death) and hospitalizations in three states – Minnesota, Texas and Ohio.
While The Today Show and CNN articles note issues related to infant formula supply chain-related shortages that have been ongoing, there are currently no mentions of hoarding or shortages reported related to the Abbott infant formula recall and FDA's related advisory. Stating:

- *"The FDA warning comes amidst a baby formula shortage. Major chains like CVS, Walmart and Target are currently battling supply issues."* (The Today Show)
- *"The US is facing a shortage of baby formula.*

According to market research firm IRI, stores' infant formula inventories in mid-January were down 17% from where they were in mid-February 2020, just before the pandemic hit US shores.

The Infant Nutrition Council of America, whose members include the largest formula makers Abbott Nutrition, Reckitt Benckiser and Gerber Products Co., said earlier this month that manufacturers were working to quickly ensure availability and access to infant formulas.

In a statement, the group acknowledged reports of challenges across the supply chains, including impacts on transportation, labor and logistics.

'Members of INCA are committed to meeting the needs of families who rely on infant formula — it is their top priority,' the group said." (CNN)

Media Coverage

FDA warns about some powdered infant formula amid investigation of 4 illnesses (ABC News)

Date: February 17, 2022
Good Morning America

The Food and Drug Administration is warning consumers not to use certain powdered infant formulas made at Abbott Nutrition's Sturgis, Michigan, facility amid an investigation into four infant illnesses.

Parents should discard any affected formula, according to the agency. Specifically, the FDA is advising consumers not to use Similac, Alimentum or EleCare powdered infant formulas if: **the first two digits of the code are 22 through 37, and the code on the container contains K8, SH or Z2, and the expiration date is 4-1-2022 (APR 2022) or later.**

"As a result of the ongoing investigation, along with the U.S. Centers for Disease Control and Prevention and state and local partners, the FDA is alerting consumers to avoid purchasing or using certain powdered infant formula products produced at this facility," a press release stated.

"This is an ongoing investigation, and the firm is working with the FDA to initiate a voluntary recall of the potentially affected product," it said, noting the FDA has "initiated an onsite inspection at the facility."

In a press release, the FDA announced it is investigating consumer complaints of Cronobacter sakazakii and Salmonella Newport infections that resulted in four infant illnesses and hospitalizations in three states -- Minnesota, Texas and Ohio. Cronobacter may have contributed to a death in one case, according to the report.

According to the FDA, Cronobacter bacteria can cause life-threatening infections such as sepsis or meningitis.

"Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths and abnormal movements. Cronobacter infection may also cause bowel damage and may spread through the blood to other parts of the body," the FDA says. "Parents and caregivers of infants who have used these products, and are concerned about the health of their child, should contact their child's health care provider."

Products made at the Sturgis, Michigan, facility are available across the U.S.

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," said Frank Yiannas, the FDA deputy commissioner for food policy and response in a press release. "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible."

The FDA will provide consumer safety information on the investigation as it becomes available.

###

FDA warns against some baby formulas after customer complaints of contamination (NBC News)

The U.S. Food and Drug Administration is cautioning parents and caregivers after recent reports of infections and one death.

By: Ariana Brockington and Samantha Kubota
The Today Show

The U.S. Food and Drug Administration announced Thursday that it is investigating certain powdered infant formula after four customer reports of children contracting serious infections.

In a news release, the FDA said infections stemming from the bacteria Cronobacter sakazakii and the strain Salmonella Newport have been linked to powdered infant formula produced in Abbott Nutrition's Sturgis, Michigan facility.

The FDA's investigation includes four infant illnesses in three states — Minnesota, Ohio and Texas — that possibly connect to these products and infections.

According to the administration, all four cases were hospitalized and one death might be connected to the Cronobacter sakazakii bacteria.

Consumers are advised to avoid certain powdered infant formula products that come from this location while the administration works with the U.S. Centers for Disease Control and Prevention as well as state and local partners to examine these reports.

The FDA says buyers should avoid Similac, Alimentum and EleCare formulas if it meets all of the following criteria:

1. The first two digits of the code are 22 through 37.
2. The code on the container contains K8, SH or Z2.
3. The expiration date is 4-1-2022 (APR 2022) or later.

Parents can also type in the code on the bottom of the package at similacrecall.com to see if their product is impacted or call +1-800-986-8540.

The FDA advisory also clarified that liquid formula products or metabolic deficiency nutrition formula are not included in the warning.

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," Frank Yiannas, FDA deputy commissioner for food policy and response, said in the news release. "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible."

According to the FDA, symptoms of Cronobacter bacteria include life-threatening infections like sepsis, meningitis, temperature changes and bowel damage. Salmonella can also cause life-threatening conditions. Other symptoms include fever, abdominal cramps, aches, fever, diarrhea.

If parents or caregivers notice an infant has these symptoms or recently consumed these products, the FDA encourages them to contact a healthcare provider and receive medical care immediately.

In a statement, Abbott Nutrition issued a voluntary recall for the impacted products and said the company's testing showed no distributed product has tested positive for the presence of either bacteria.

"Additionally, retained samples related to the three complaints for Cronobacter sakazakii tested negative for Cronobacter sakazakii," the statement said. "And the retained sample related to the complaint for Salmonella Newport tested negative for Salmonella Newport."

In a statement to TODAY, a spokesperson said Abbott Nutrition values the trust of parents to provide safe food for their kids and that it will "do whatever it takes to keep that trust and resolve this situation."

The FDA warning comes amidst a baby formula shortage. Major chains like CVS, Walmart and Target are currently battling supply issues.

Dr. Kate Lockwood, a pediatrician at Children's Hospital of Philadelphia, previously spoke to TODAY about tips parents and caregivers can use to feed their children.

Lockwood shared that doctors can request special shipments for their patients who are in need of particular formulas. She also noted that doctors can suggest a regulated breast milk bank to use.

"Sometimes smaller mom and pop stores carry formula," Lockwood said. "Think about places that might not have their shelves wiped out, like family-owned pharmacies and convenience stores."

Both Lockwood and the FDA warned against making formula at home. The agency cautioned that making formula can cause "very serious health concerns" for a baby.

# # #

Abbott recalls baby formulas after four infants reportedly fall ill

By: Sophie Reardon
Date: February 18, 2022
CBS News

Abbott voluntarily recalled several of its baby formula products after four infants reportedly got sick. The powder formulas were distributed across the country, and possibly exported to other countries, the Food and Drug Administration said.

The powder formulas impacted by the recall include Similac, Alimentum and EleCare. To identify if you have a package affected by the recall, check the number on the bottom of the container. If it starts with digits 22 through 37 and contains K8, SH or Z2, and has an expiration of April 1, 2022, or later, it should be thrown out. All of the recalled formula was produced at the company's Sturgis, Michigan, facility, the company said.

Abbott has set up a web page where you can check if your powder formula's lot number is included in the recall: https://www.similacrecall.com/us/en/product-lookup.html. Consumers can get more information at www.similacrecall.com on how to obtain a refund or replacement, or call Similac customer service at 1-800-986-8540.

The four infants, located in Texas, Ohio and Minnesota, were diagnosed with bacteria infections cronobacter sakazakii and salmonella Newport and hospitalized. One of the infants may have died of cronobacter, according to the FDA.

The company said it has tested samples of the formula from the plant, as well as samples from the four complaints, and all of the tests have come back negative. The company did say it found evidence of cronobacter in the Michigan plant in non-product areas.

The FDA said that several environment samples from the plant have tested positive for cronobacter.

Cronobacter bacteria can cause sepsis or meningitis, which can be severe and life-threatening illnesses, according to the FDA. Symptoms of sepsis and meningitis in an infant include poor feeding, irritability, temperature changes, jaundice, grunting breaths and abnormal movements.

Salmonella can cause gastrointestinal illness and fever called salmonellosis, the FDA said. Symptoms include diarrhea, fever and abdominal cramps. Severe cases of salmonellosis can cause a high fever, aches, headaches, lethargy, rashes and blood in urine or stool. It can become fatal.

The investigation, which includes the Centers for Disease Control and Prevention and the FDA, is ongoing.

"We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible," said Frank Yiannas, FDA deputy commissioner for food policy and response.

###

FDA says parents should avoid certain powdered baby formula after reports of 4 bacterial infections

By: Aya Elamroussi
Date: February 18, 2022
CNN

The US Food and Drug Administration on Thursday cautioned people to avoid certain powdered infant formulas that may be tied to bacterial infections in four babies who were hospitalized.

The infections, which may have led to the death of one baby, were found in Texas, Ohio and Minnesota, the FDA said in a news release.
Three infections stemmed from Cronobacter, a bacteria that can cause severe, life-threatening infections or inflammation of the membranes that protect the brain and spine. The third infection was from Salmonella, a group of bacteria that can cause digestive illness and fever.
"Parents and caregivers of infants who have used these products, and are concerned about the health of their child, should contact their child's health care provider," the FDA said in the news release.
The FDA is advising that people should avoid using Similac, Alimentum or EleCare powdered infant formulas if the first two digits of the code are 22 through 37; the code on the container contains K8, SH or Z2; the expiration date is April 1, 2022, or later.
The infections stem from infant powdered formulas that were made at Abbott Nutrition's facility in Sturgis, Michigan. The company said Thursday that it's recalling the formulas in question.
"During testing in our Sturgis, Mich., facility, we found evidence of Cronobacter sakazakii in the plant in non-product contact areas. We found no evidence of Salmonella Newport," Abbott Nutrition said in a news release. "Importantly, no distributed product has tested positive for the presence of either of these bacteria, and we continue to test."
The company noted that its testing did not find Cronobacter sakazakii or Salmonella in the retained samples related to the complaints. The investigation is underway.
The US is facing a shortage of baby formula.
According to market research firm IRI, stores' infant formula inventories in mid-January were down 17% from where they were in mid-February 2020, just before the pandemic hit US shores.
The Infant Nutrition Council of America, whose members include the largest formula makers Abbott Nutrition, Reckitt Benckiser and Gerber Products Co., said earlier this month that manufacturers were working to quickly ensure availability and access to infant formulas.
In a statement, the group acknowledged reports of challenges across the supply chains, including impacts on transportation, labor and logistics.
"Members of INCA are committed to meeting the needs of families who rely on infant formula — it is their top priority," the group said.

# # #

Baby formula recall 2022: FDA warns consumers not to use select Similac, Alimentum and EleCare

By: Kelly Tyko
Date: February 17, 2022
USA Today

Abbott Nutrition is voluntarily recalling three types of infant formula after four babies became sick with bacteria infections after consuming the products.

The recall, announced Thursday, is for select lots of Similac, Alimentum and EleCare formulas that were manufactured at an Abbott facility in Sturgis, Michigan.

The Food and Drug Administration warned consumers not to use or purchase the formulas or certain powdered infant formula produced at the facility.

"The FDA is investigating complaints of four infant illnesses from three states," the agency said in a statement on Thursday. "All four cases related to these complaints were hospitalized and Cronobacter may have contributed to a death in one case."

Infants sick with Cronobacter sakazakii or salmonella

Three of the babies were sick with Cronobacter sakazakii and one had Salmonella Newport, the FDA said.

Cronobacter bacteria can cause severe, life-threatening sepsis infections or meningitis while salmonella can cause gastrointestinal illness and fever, according to the FDA.

"We deeply regret the concern and inconvenience this situation will cause parents, caregivers and health care professionals," Joe Manning, Abbott executive vice president, nutritional products, said in a statement.

The FDA said it initiated an onsite inspection at the facility and findings to date include several positive "Cronobacter sakazakii results."

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," said Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response, in a statement.

Abbott recall: What products are recalled?

The products under recall include Similac, Alimentum and EleCare powdered infant formulas. Check a multidigit number on the bottom of the container to know if your product is included:

- The first two digits of the code are 22 through 37; and
- The code on the container contains K8, SH or Z2; and
- The expiration date is 4-1-2022 (APR 2022) or later.

# # #

FDA urgently warns against using these baby formulas after infant dies (Associated Press)

Correspondent: By Associated Press
Date: February 18, 2022
The New York Post

US health officials warned parents not to use three popular powdered infant formulas manufactured at an Abbott plant in Michigan that investigators recently linked to bacterial contamination.

The Food and Drug Administration said Thursday it is investigating four reports of infants who were hospitalized after consuming the formula, including one who died. The agency said one of the cases involved salmonella and three involved Cronobacter sakazakiim, a rare but dangerous germ that can cause blood infections and other serious complications.

Abbott, one of the country's largest infant formula makers, said it is recalling all potentially affected products manufactured at the facility. The recall affects certain lots of Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later. The product was distributed throughout the US and overseas, the company said in a statement.

FDA staff are inspecting Abbott's plant in Sturgis, Michigan, where environmental samples tested positive for the Cronobacter bacteria. Inspectors have also uncovered potential manufacturing problems, and records showing the destruction of formula due to bacterial contamination.

"We're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible," said FDA Deputy Commissioner Frank Yiannas.

The FDA said it is working with federal and local authorities in Minnesota, Ohio and Texas — the states where the infant infections were reported.

Abbott could not specify how many units the recall includes, but brands like Similac are among the best-selling formulas in the US and overseas.

"We value the trust parents place in us for high quality and safe nutrition and we'll do whatever it takes to keep that trust and resolve this situation," a company spokeswoman said in a statement.

Abbott said parents can identify the recalled products by examining the number on the bottom of each container. The affected formulas have a number starting with 22 through 37, contain K8, SH, or Z2 and have an expiration date of April 1, 2022 or later. The company has also set up a website where parents can check if their products have been recalled.

The company said its own testing of finished product didn't detect any contamination. The recall does not affect liquid infant formulas or any other Abbott products.

# # #

Stop using these baby formulas, the FDA says, after 4 infants are hospitalized

By: Rina Torchinksy
Date: February 17, 2022
NPR

The U.S. Food and Drug Administration is advising consumers not to use some powdered baby formulas after identifying four bacterial infections linked to the products. One of the cases was fatal.
Abbott Nutrition, which makes the Similac, Alimentum and EleCare brands, on Thursday issued a voluntary recall of certain formulas manufactured at its plant in Sturgis, Mich., where the formulas involved in the infections were produced.

You can check if your powdered formula is affected by inspecting the code printed near the expiration date. Affected products have a code beginning in 22 through 37, contain K8, SH, or Z2 and an expiration date of April 1, 2022, or later.

Liquid baby formula, and all other products produced by Abbott Nutrition, are not affected.

Abbott Nutrition said it is cooperating with the FDA investigation into the three Cronobacter sakazakiim infections and one salmonella infection, all of which required hospitalization. The one fatal case has not been confirmed to be solely related to a Cronobacter infection, according to the FDA.

The FDA said environmental samples from the facility have yielded positive results for the Cronobacter bacteria, but there have been no reports of salmonella so far. A review of Abbott's records show that the company has destroyed products in the past due to the presence of Cronobacter.
Cronobacter infections are rare, but can be especially dangerous for newborn babies.

Symptoms of a Cronobacter infection include poor feeding, jaundice and grunting breaths, according to the FDA. Those infected with salmonella might experience fever, diarrhea and abdominal cramps.
"We value the trust parents place in us for high quality and safe nutrition," Abbott said in a statement provided to NPR. "We'll do whatever it takes to keep that trust and resolve this situation."

# # #

FDA learned of suspected infant formula illness four months before recall

The Minnesota Department of Health investigated a case of an infant who was sickened by Cronobacter sakazakii in September 2021, the state agency told POLITICO.

Correspondent: Helena Bottemiller Evich
Date: February 18, 2022
Politico

The FDA first received a report of a foodborne illness suspected to be linked to infant formula in September — four months before issuing a recall of three major brands this week after four babies were hospitalized and one died, according to a state agency.

The sweeping recall on Thursday of Similac, Alimentum and EleCare — amid a widespread shortage of infant formula on store shelves — comes after reports of illnesses came to FDA and the Centers for Disease Control and Prevention between September and December. The Minnesota Department of Health investigated a case of an infant who was sickened by Cronobacter sakazakii in September 2021, the state agency told POLITICO.

State health officials in Minnesota — a state known for its keen ability to crack foodborne illness investigations — knew that the infant had consumed powdered formula produced at an Abbott Nutrition facility in Sturgis, Mich., and shared this information with FDA and CDC in September, the agency said. FDA inspectors later found Cronobacter sakazakii at the plant.

The FDA did not respond to questions about its timeline. The agency has shared details on which lots of formula have been recalled here. The CDC did not immediately respond to a request for comment on the length of the investigation timeline.

The Minnesota baby who got sick in September survived but was hospitalized for 22 days, the state told POLITICO. Cronobacter sakazakii is a rare but serious foodborne pathogen that can cause "severe, life-threatening infections" including sepsis and meningitis as well as bowel damage, according to FDA.

Pinpointing the source of foodborne outbreaks is extremely difficult because most people eat a wide variety of foods and do not remember exactly what they ate days or weeks after the fact. But foodborne illnesses in infants are much simpler to solve. Babies typically are consuming one source of nutrition: breast milk or infant formula, or in some cases both.

"It often takes time to gather enough information to put the pieces of a puzzle together — or at least enough pieces to make clear the actions needed to protect public health," said Doug Schultz, a spokesperson for the Minnesota Department of Health, explaining why one illness might not spark a recall. State agencies can't institute national recalls; only FDA has that power.

"As part of Minnesota's investigation of its case, exposure information was collected, including information about the formula given to the infant (lot numbers etc)," Schultz said. "This information was shared with CDC and FDA."

Two more reports of Cronobacter sakazakii happened some time between September and December, according to FDA, though the agency did not respond to questions about when exactly it received them. The agency also received a complaint about a Salmonella Newport illness. All four infants who were hospitalized were reported to have consumed powdered formula from the Sturgis facility. One death has been reported, but FDA said it "has not been confirmed to be solely attributable to Cronobacter infection."

The FDA issued its warning to consumers and a voluntary recall from Abbott Nutrition the evening of February 17. The agency also initiated an inspection of the Sturgis facility in response to the illnesses, but it has not specified when this inspection took place.

"FDA has initiated an onsite inspection at the facility," the agency said in its Thursday warning. "Findings to date include several positive Cronobacter results from environmental samples taken by FDA, and adverse inspectional observations by FDA investigators. A review of the firm's internal records also indicate environmental contamination with Cronobacter sakazakii and the firm's destruction of product due to the presence of Cronobacter."

FDA said Thursday its investigation is "ongoing."

A spokesperson for Abbott Nutrition said that the company received complaints between September 2021 and the end of January 2022. "In each case, we thoroughly investigated each complaint and communicated with the FDA, in line with our standard quality practices," the spokesperson said.

"We value the trust parents place in us for high quality and safe nutrition and we'll do whatever it takes to keep that trust and resolve this situation," the spokesperson said in an email.

The spokesperson noted that all infant formula products are tested for both pathogens and must test negative before any product is sold.

Microbiological testing is an important food safety tool, but it can miss contamination problems.

In 2017, an inspector general report found that FDA had serious deficiencies with its food recall process. "Recalls were not always initiated promptly because FDA does not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls," the report concluded.

The agency has since tried to shore up its foodborne outbreak response. In December, the agency released a plan aimed at solving outbreaks faster and said it had expanded its rapid response teams to help federal and state officials work better together, among other changes.

# # #

FDA: Do not use recalled infant formulas tied to infections (Associated Press)

By: Matthew Perrone
Date: February 18, 2022
AP

WASHINGTON (AP) — U.S. health officials warned parents on Thursday not to use three popular powdered infant formulas manufactured at an Abbott plant in Michigan that investigators recently linked to bacterial contamination.

The Food and Drug Administration said it is investigating four reports of infants who were hospitalized after consuming the formula, including one who died. The agency said one of the cases involved salmonella and three involved Cronobacter sakazakiim, a rare but dangerous germ that can cause blood infections and other serious complications.

Abbott, one of the country's largest infant formula makers, said it is recalling all potentially affected products manufactured at the facility. The recall affects certain lots of Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later. The product was distributed throughout the U.S. and overseas, the company said in a statement.

FDA staff are now inspecting Abbott's plant in Sturgis, Michigan, where environmental samples tested positive for the Cronobacter bacteria. Inspectors have also uncovered potential manufacturing problems, and past records showing the destruction of formula due to bacterial contamination.

"We're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible," said FDA Deputy Commissioner Frank Yiannas.

The FDA said it is working with federal and local authorities in Minnesota, Ohio and Texas— the states where the infant infections were reported.

Abbott could not specify how many units the recall includes, but brands like Similac are among the best-selling formulas in the U.S. and overseas.

"We value the trust parents place in us for high quality and safe nutrition and we'll do whatever it takes to keep that trust and resolve this situation," a company spokeswoman said in a statement.

Abbott said parents can identify the recalled products by examining the number on the bottom of each container. The affected formulas have a number starting with 22 through 37, contain K8, SH, or Z2 and have an expiration date of April 1, 2022 or later. The company has also setup a website where parents can check if their products have been recalled: https://www.similacrecall.com/us/en/home.html.

The company said its own testing of finished product didn't detect any contamination. The recall does not affect liquid infant formulas or any other Abbott products.

# # #

FDA warns against using some infant formulas after hospitalizations, death (Nextar Media Wire)

By: Addy Bink
Date: February 17, 2022
News Nation

(NEXSTAR) – Federal regulators are warning consumers to stop using infant formula that is believed to have sent four children to the hospital and may have contributed to a death in one case. An investigation is now underway.

Consumer complaints of Cronobacter sakazakii and Salmonella Newport infections are now under investigation, the U.S. Food and Drug Administration announced Thursday. All of the reported cases are said to have consumed a powdered infant formula from Abbott Nutrition's Sturgis, Michigan, facility.

According to the FDA, four cases of infants falling ill (three with Cronobacter and one with salmonella) in three states – Minnesota, Ohio, and Texas – have been reported. All four were hospitalized and Cronobacter may have contributed to the death of one infant.

"We value the trust parents place in us for high quality and safe nutrition and we'll do whatever it takes to keep that trust and resolve this situation," Abbott said in a comment to Nexstar.

Abbott said in a news release that the company does routine testing for Cronobacter sakazakii and other pathogens. A recent test found evidence of Cronobacter sakazakii only in "non-product contact areas" of the plant and no evidence of Salmonella Newport. Cronobacter germs exist in the environment and have been found in soil, processed cheese, meats and in herbs, among other places.

Abbott went on to say that no distributed product had tested positive for either pathogen, including samples from the same lots linked to the cases under investigation.

Cronobacter bacteria can cause severe, life-threatening infections, such as sepsis or meningitis, according to the CDC. Cronobacter infections are often serious in infants and can lead to death. Salmonella, a group of bacteria, can cause gastrointestinal illness and fever.

While the firm is working with the FDA to initiate a voluntary recall, federal officials are now encouraging consumers to avoid purchasing or using certain formulas from the Michigan facility. Affected powdered formulas include Similac, Alimentum, and EleCare with the first two digits of the code are 22 through 37; the code has K8, SH, or Z2; and if the expiration date is 4-1-2022 or later.

Below is an image of the code found on one of the affected products.

These products were sold nationwide.

The FDA says it found several positive Cronobacter sakazii results from environmental samples taken at the Michigan facility, as well as "adverse inspectional observations by the FDA investigators."

If you have used these products and are concerned about the health of your child, the FDA recommends speaking with your health care provider. If your child begins experiencing symptoms of Cronobacter or salmonella, notify your healthcare provider and seek medical attention for your child immediately.

The FDA says the investigation remains ongoing.

Abbott issued the following guidance for parents:

To find out if the product you have is included in this recall, visit similacrecall.com and type in the code on the bottom of the package, or call +1-800-986-8540 (U.S.) and follow the instructions provided. No action is needed for previously consumed product. If you have questions about feeding your child, contact your healthcare professional.

Some product was distributed to countries outside the U.S. A list of these products can be found at similacrecall.com.

###

Three baby formulas recalled by Abbott Nutrition amid warnings from FDA

By: Olafimihan Oshin
Date: February 17, 2022
The Hill

Abbott Nutrition on Thursday announced a recall of three of its infant formulas after four babies who consumed the company's products were reported to have been hospitalized for bacterial infections.

The recall is for specific lots of the company's Similac, Alimentum and EleCare formulas that were produced by its Sturgis, Mich., facility, USA Today reported.

This comes as the Food and Drug Administration (FDA) advised consumers in a release on Thursday not to use certain powdered infant formula products produced at the facility.

The agency said it was investigating complaints that the four infants in three states who were said to have consumed powdered infant formula produced at the facility were reported to have Cronobacter sakazakii and Salmonella Newport infections.

"All four cases related to these complaints were hospitalized and Cronobacter may have contributed to a death in one case," the FDA wrote in the release.

The FDA also said it had initiated an onsite inspection at the facility.

“As this is a product used as the sole source of nutrition for many of our nation’s newborns and infants, the FDA is deeply concerned about these reports of bacterial infections,” FDA Deputy Commissioner for Food Policy and Response Frank Yiannas said in a statement.

“We want to reassure the public that we’re working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible,” Yiannas continued.

Abbott Nutrition on Thursday announced a recall of three of its infant formulas after four babies who consumed the company's products were reported to have been hospitalized for bacterial infections.

The recall is for specific lots of the company's Similac, Alimentum and EleCare formulas that were produced by its Sturgis, Mich., facility, USA Today reported.

This comes as the Food and Drug Administration (FDA) advised consumers in a release on Thursday not to use certain powdered infant formula products produced at the facility.

The agency said it was investigating complaints that the four infants in three states who were said to have consumed powdered infant formula produced at the facility were reported to have Cronobacter sakazakii and Salmonella Newport infections.

"All four cases related to these complaints were hospitalized and Cronobacter may have contributed to a death in one case," the FDA wrote in the release.

The FDA also said it had initiated an onsite inspection at the facility.

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," FDA Deputy Commissioner for Food Policy and Response Frank Yiannas said in a statement.

"We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible," Yiannas continued.

The Centers for Disease Control and Prevention and state and local partners are also contributing to the investigation, according to the FDA.

In a statement to USA Today, Abbott Nutrition apologized for the inconvenience of the recall to consumers.

"We deeply regret the concern and inconvenience this situation will cause parents, caregivers and health care professionals," Abbott Nutrition Executive Vice President Joe Manning said, the outlet reported.

###

FDA Warns Against Using Recalled Baby Formulas Tied To Infections

By: Associated Press and Ash-har Quraishi
Date: February 18, 2022
Newsy

Officials say bacterial contamination has been detected in certain lots of Similac, Alimentum and EleCare.
U.S. health officials warned parents on Thursday not to use three popular powdered infant formulas manufactured at an Abbott plant in Michigan that investigators recently linked to bacterial contamination.

The Food and Drug Administration said it is investigating four reports of infants who were hospitalized after consuming the formula, including one who died. The agency said one of the cases involved salmonella and three involved Cronobacter sakazakiim, a rare but dangerous germ that can cause blood infections and other serious complications.

Abbott, one of the country's largest infant formula makers, said it is recalling all potentially affected products manufactured at the facility. The recall affects certain lots of Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later. The product was distributed throughout the U.S. and overseas, the company said in a statement.

FDA staff are now inspecting Abbott's plant in Sturgis, Michigan, where environmental samples tested positive for the Cronobacter bacteria. Inspectors have also uncovered potential manufacturing problems, and past records showing the destruction of formula due to bacterial contamination.

The FDA said it is working with federal and local authorities in Minnesota, Ohio and Texas— the states where the infant infections were reported.

Abbott could not specify how many units the recall includes, but brands like Similac are among the best-selling formulas in the U.S. and overseas.

The company said parents can identify the recalled products by examining the number on the bottom of each container. The affected formulas have a number starting with 22 through 37, contain K8, SH, or Z2 and have an

expiration date of April 1, 2022 or later. The company has also setup a website where parents can check if their products have been recalled: https://www.similacrecall.com/us/en/home.html.

# # #

Formula Recall: How to Check if Your Abbott Baby Formula Is Safe

If you use certain types of Similac, Alimentum or EleCare, you may need to throw them away. Here's how to see if your baby's formula is affected by the recall.

By: Alison DeNisco Rayome
Date: February 18, 2022
CNET

Baby formula-maker Abbott Nutrition has issued a voluntary recall on select types of powder formulas Similac, Alimentum and EleCare formulas, the US Food and Drug Administration said Thursday. The company issued the recall after receiving four complaints of babies becoming hospitalized with bacterial infections, one of whom died.

Three of the complaints were for Cronobacter sakazakii, which can cause fever, poor feeding, excessive crying, low energy and other serious symptoms, according to the FDA. One complaint was for Salmonella Newport, which can cause diarrhea, fever and abdominal cramps, along with other more severe side effects, including high fever.

All of the reported cases of illness have stemmed from powdered formula produced in Abbott Nutrition's facility in Sturgis, Michigan. The company has found evidence of Cronobacter sakazakii in that facility, but not Salmonella Newport, though the investigation is ongoing, according to the FDA.

Though this is scary to hear, parents generally shouldn't worry. Abbott said that it conducts routine testing for these bacteria, and that no distributed product has tested positive for the presence of either bacteria.

Bottom line: It's unlikely that your baby will get sick, even if you have been using one of the recalled formulas. The recall also doesn't include liquid formulas or metabolic deficiency nutrition formulas. But if your baby is experiencing any of these symptoms, you should contact your health care provider immediately.

How to check if your baby formula is impacted by the recall

There's an easy way to check if your Similac, Alimentum or EleCare formula is included in this recall. Here's how:

1. Flip your container of formula over, and find the seven- to nine-digit code located above the Use By date. This code is called the Lot Number.

2. Go to Similac's recall website, and enter the Lot Number. The site will tell you if it's been recalled. You can also call 800-986-8540 to find out. Or, if you'd rather check manually, your formula is part of the recall if all three of the following are true:

- The first two digits of the Lot Code are 22 through 37
- The Lot Code contains K8, SH or Z2
- The expiration date is April 2022 or later

3. If your formula is impacted by the recall, you should throw it away. You can visit SimilacRecall.com for a refund or a replacement.

If you were affected by the recall and need formula to feed your baby, you should contact your health care provider.

No matter what formula you use, you should always follow the Centers for Disease Control and Prevention's instructions for proper preparation, handling and storage. This includes washing your hands before preparing formula, and using prepared formula within one hour from when feeding starts.

###

Baby formula recall: Stop feeding infants with these products, FDA warns
By: Katherine Rodriguez
Date: February 18, 2022
NJ.com

Pharmaceutical company Abbott laboratories is recalling certain types of baby formulas made at a Michigan plant because four consumers said it gave their infants bacterial infections.
Abbott will recall certain Alimentum, EleCare, and Similac powdered formulas that were manufactured at the Sturgis, Michigan plant.

According to the FDA, the affected products have the following codes and expiration dates:

- the first two digits of the code are 22 through 37; and
- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.

The FDA added that this recall does not include liquid formulas.

If parents and caregivers of infants have given the recalled formula to their infants and are concerned about the health of their children, the agency urges them to contact their pediatricians or other health care providers on behalf of their children.

Consumers complained their infants were infected with the *Cronobacter sakazakii* bacteria or *Salmonella Newport* bacteria. All the reported cases consumed powdered infant formula made at Abbott's Sturgis, Mich., production facility, according to the U.S. Food and Drug Administration (FDA).
The FDA said in a statement that investigations of consumer complaints were already in progress.

"All four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case," the agency said.
Cronobacter can cause premature infant death, among other serious complications, according to the Centers for Disease Control and Prevention (CDC).

###

FDA Warns Parents Not To Use Some Similac, Alimentum And EleCare Powdered Infant Formula

By: CBS Boston Staff
Date: February 18, 2022
CBS Boston

BOSTON (CBS) – The Food and Drug Administration is asking parents to stop using some specific baby formulas after reports an infant died and three others got sick.

The FDA is investigating whether the products contain dangerous bacteria.

Parents should check any powder formulas labeled Similac, Alimentum, or EleCare.

Throw the product out if the first two digits on the container are between 22 and 37 and the code contains K8, SH or Z2 and the expiration date is April 2022 or later.

For more information, click here.

###

Recall: FDA warns parents to check labels of powder baby formula

By: News 12 Staff
Date: February 18, 2022
News 12 Brooklyn

Parents, if you use powder baby formula the Food and Drug Administration is warning that some popular brands may be contaminated.

Products labeled Similac, Alimentum and EleCare may be contaminated with dangerous bacteria.

From the Abbott news release:

What Parents and Caregivers Should Do

The products under recall have a multidigit number on the bottom of the container starting with the first two digits 22 through 37, contains K8, SH, or Z2 and with an expiration date of April 1, 2022, or after. To find out if the product you have is included in this recall, visit similacrecall.comExternal Link Disclaimer and type in the code on the bottom of the package, or call +1-800-986-8540 (U.S.) and follow the instructions provided.

No action is needed for previously consumed product. If you have questions about feeding your child, contact your healthcare professional.Some product was distributed to countries outside the U.S. A list of these products can be found at similacrecall.com.

Those products were made in Sturgis, Michigan.

The FDA says parents should avoid using formula if the first two digits on the infant formula's code are between 22-37 and if expiration date is April 2022 or later.

Check out fda.gov for more details.

###

FDA Warns Against Using Certain Powder Infant Formulas

Abbott voluntarily recalled several of its baby formula products after four infants reportedly got sick. The powder formulas were distributed across the country, and possibly exported to other countries, the Food and Drug Administration said.

By: Broadcast
Date: February 18, 2022
CBS Sacramento

###

Urgent warning issued about infant formula and Cronobacter, Salmonella infections

By: News Desk
Date: February 17, 2022
Food Safety News (FSN)

The FDA, along with CDC and state and local partners are investigating four consumer complaints of infant illness related to infant formula products from Abbott Nutrition's Sturgis, MI, facility.

As of today, four infant illnesses have been reported. Three are cronobacter infections and one is a Salmonella infection. One death has been reported. Infants became ill between Sept. 6, 2021, and Dec. 2021. Sick people reside in Minnesota, Ohio, and Texas.

The implicated product was distributed nationwide and has expiration dates through 2022. The company has initiated a recall.

All of the sick infants are reported to have consumed powdered infant formula (IF) produced from Abbott Nutrition's Sturgis, MI, facility. All four patients were hospitalized and Cronobacter is believed to have contributed to a death in one case, according to the Food and Drug Administration.

The FDA has initiated an onsite inspection at the facility. Findings to date include several positive Cronobacter results from environmental samples taken by FDA and adverse inspectional observations by FDA investigators. A review of the firm's internal records also indicates environmental contamination with Cronobacter sakazakii and the firm's destruction of products because of the presence of Cronobacter.

The FDA is issuing this advisory to alert consumers to avoid purchasing or using certain powdered infant formula produced in the Sturgis, MI, facility.

This is an ongoing investigation and the firm is working with the FDA to initiate a voluntary recall of the potentially affected products. FDA is continuing to investigate.

Recommendation

The FDA is advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas if:

- the first two digits of the code are 22 through 37 and
- the code on the container contains K8, SH, or Z2, and
- the expiration date is 4-1-2022 (APR 2022) or later.

The code is printed on the product packaging near the expiration date. Additional information on products made by Abbott Nutrition is available on their website: https://abbottnutrition.com/infant-and-new-mother.

The FDA advisory does not include liquid formula products or any metabolic deficiency nutrition formulas.

Products made at the Sturgis facility can be found across the United States and were likely exported to other countries as well.

These powdered infant formulas have the potential to be contaminated with Cronobacter, a bacterium that can cause severe foodborne illness primarily in infants. Cronobacter infections are rare but are especially high risk for newborn infants (see symptoms below).

Parents and caregivers should never dilute infant formula and should not make or feed homemade infant formula to infants.

More information on *Cronobacter* and infant formula is available on CDC's website.

Cronobacter bacteria can cause severe, life-threatening infections (sepsis) or meningitis (inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths, and abnormal movements. Cronobacterinfection may also cause bowel damage and may spread through the blood to other parts of the body.

If your child is experiencing any of these symptoms, you should notify your child's healthcare provider and seek medical care for your child immediately. Healthcare providers and health departments are encouraged to report any confirmed cases of Cronobacter sakazakii to CDC.

# # #

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Friday, February 18, 2022 1:11 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Thanks all,

Our updates are now live: https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022

From: Newhart, Corinne
Sent: Friday, February 18, 2022 12:12 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

An update to our Advisory will be posted shortly to reflect the recall notice from the firm.

Final language is attached and I will provide the link once we are live.

Thanks all,
Corinne

From: Newhart, Corinne
Sent: Thursday, February 17, 2022 5:12 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>;

Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

We are now live:

Advisory: FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) | FDA

CORE Investigation Table: https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks

The PR will be live shortly

Thanks all,
Corinne

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 4:15 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-

Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

Below is our final language, we are still targeting 5pm posting. I will send the link once we are live.

FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022)

Do not use certain powdered infant formulas produced at Abbott Nutrition's Sturgis, MI facility

The FDA, along with CDC and state and local partners are investigating four consumer complaints of infant illness related to products from Abbott Nutrition's Sturgis, MI facility received from 9/6/2021 to 12/18/2021. All of the cases are reported to have consumed powdered infant formula (IF) produced from Abbott Nutrition's Sturgis, MI facility. These complaints include three reports of *Cronobacter sakazakii* infections and one report of *Salmonella* Newport infection in infants. All four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case.

FDA has initiated an onsite inspection at the facility. Findings to date include several positive *Cronobacter* results from environmental samples taken by FDA, and adverse inspectional observations by FDA investigators. A review of the firm's internal records also indicate environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*.

FDA is issuing this advisory to alert consumers to avoid purchasing or using certain powdered infant formula produced in the Sturgis, MI facility.

This is an ongoing investigation and the firm is working with the FDA to initiate a voluntary recall of potentially affected product. FDA is continuing to investigate and will update this advisory should additional consumer safety information become available.

Recommendation

The FDA is advising consumers not to use Similac (all varieties) or Elecare powdered infant formulas if:

- the first two digits of the code are 22 through 37 and
- the code on the container contains K8, SH, or Z2, and
- the expiration date is 4-1-2022 (APR 2022) or later.

The code is printed on the product packaging near the expiration date (see product image below). Additional information on products made by Abbott Nutrition is available on their website: https://abbottnutrition.com/infant-and-new-mother

Products that do not contain the information listed above are not impacted by this advisory. This advisory does not include liquid formula products. Consumers should continue to use all product not covered by this advisory.

Products made at the Sturgis facility can be found across the United States and were likely exported to other countries as well.

These powdered infant formulas have the potential to be contaminated with *Cronobacter*, a bacterium that can cause severe foodborne illness primarily in infants. *Cronobacter* infections are rare but are especially high risk for newborn infants (see symptoms below).

Parents and caregivers should never dilute infant formula and should not make or feed homemade infant formula to infants.

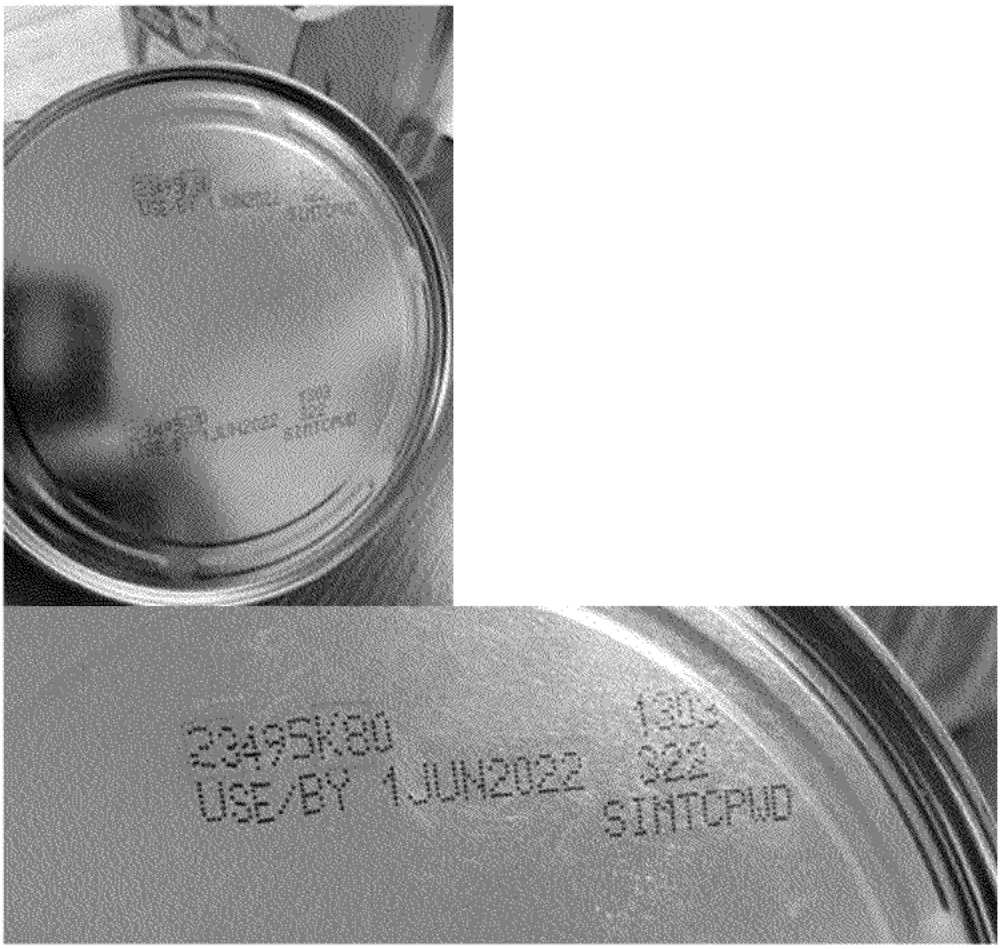
If your regular formula is not available, contact your child's healthcare provider for recommendations on changing feeding practices.

More information on *Cronobacter* and infant formula is available on CDC's website.

Cronobacter bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths, and abnormal movements. Cronobacter infection may also cause bowel damage and may spread through the blood to other parts of the body.

If your child is experiencing any of these symptoms, you should notify your child's healthcare provider and seek medical care for your child immediately. Healthcare providers and health departments are encouraged to report any confirmed cases of *Cronobacter sakazakii* to CDC.

Product Image



Useful Links

- CDC information on *Cronobacter* and infant formula
- What is *Salmonella*?
- Food Safety Tips for Consumers & Retailers During an Outbreak
- Who to Contact

Case Counts

Total Adverse Events: 4 (3 *Cronobacter*, 1 *Salmonella*)
Hospitalizations: 4
Reported Deaths: 1*
Adverse Event Dates: 9/6/2021 – 12/18/2021
States with Adverse Events: MN (1), OH (1), TX (2)
Product Distribution: Nationwide and International
*One death has been reported but has not been confirmed to be solely attributable to *Cronobacter* infection.

Who to Contact

If your child has symptoms you should contact their health care provider to report their symptoms and seek care immediately.

To report a **complaint** or **adverse event** (illness or serious allergic reaction), you can

- Call an FDA Consumer Complaint Coordinator if you wish to speak directly to a person about your problem.
- Complete an electronic Voluntary MedWatch form online.
- Complete a paper Voluntary MedWatch form that can be mailed to FDA.

Visit www.fda.gov/fcic for additional consumer and industry assistance.

Submit Questions Electronically

Get E-mail Updates

Follow Us on Twitter

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 1:16 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

Our Advisory and Press Release are now scheduled for 5pm today.

Final text will be provided in advance of posting.

Thank you all,
Corinne

From: Newhart, Corinne
Sent: Wednesday, February 16, 2022 9:03 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A.

<Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OO-OFBA-Congressional-Government <OO-OFBA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Cathy Abi-Khattar <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; OFVM-CFSAN-CVM-OEP <OFVM-CFSAN-CVM-OEP@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

This email is to inform leadership that we will be issuing a new advisory today on the investigation of three consumer complaints of *Cronobacter sakazakaii* infections and one complaint of *Salmonella* Newport infection.

The advisory is in clearance now and we are targeting a release before COB today, to align with the addition of this investigation to the CORE Investigation Table.

Those who need to clear have or will be contacted separately.

If you have any questions or concerns, please let me know. I will share final language with this group in advance of posting and the link once we are live.

Thanks all,
Corinne

From: Newhart, Corinne [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=656A525A42E547959EFEA21AB442BCD6-CORINNE.NEW]
Sent: 2/18/2022 12:12:16 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Farrar, Jeff A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c862ce01b6714d4c9c5057306240469e-Jeff.Farrar]; Prater, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291b4eab842148baba96df3bd8c31058-DPRATER]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Ramos, Melissa * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30d58cc38d04aa3894a8de1d0113efb-Melissa.Ram]; Smith-Dulley, Jasmine * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa7cb8415b5a4e259866911bf4caed7d-Jasmine.Smi]
CC: Morris, Larry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591baaec2f0841a9b712b0c864bfc8f5-Larry.Morri]; Summers, Tracy S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d149bd080a243e2ae15ebdec8d15551-TSUMMERS]; Moxley, Shera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dbddbf813674d38ac4a43176e2398e4-Shera.Moxle]; CFSAN-OCD-CPES [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85ce6b6b5764222bd3060dcdd1f5976-CFSAN-OCD-C]; CFSANTradepress [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3786796db71b4899877e851ca8dcd9ce-CFSANTradep]; CFSANEXECSEC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=468d52748b974fa598d4dfb4a83ab38f-OFVM-CFSAN-]; OCA-OPLIA-Congressional-Government [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadd1dfbd5a648a186d6c00d81d6d0f3-OO-OFBA-Con]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Das, Sharmi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebe21fc31d6d46cf8540275f6ff52c73-Samarpita.D]; Abi-Khattar, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a37f6065cf544cb91915274e0203d08-Cathy.Ghale]; CFSAN-Webmaster [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c802bd23bcf4276b81406b691b66ace-CFSAN-Webma]; Lehman, Kristen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=094248c8546e40b898eae67f7f86fc94-Kristen.Leh]; Benton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d254dc9aa5f543698fae327f4ab7552d-Denise.Bent]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Lockeed, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2fe9a22e8f940fa8761fad18ef37dd0-Matthew.Loc]; Goitom, Mahlet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3476ef7044d54ad88f0d8c8639fdc9d8-Mahlet.Goit]; Hattis, Daniel

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; Earley, Rosemary
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05737f759eb54e9188cb16cbbe467d12-Rosemary.Ea]; Vera, Rita
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d9b116472abd409995f72f68170a1f16-Rita.Vera]; Price, Deborah S
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6eae4da0f0634de3b9f5a200f4f356e5-DPRICE]; Iguina, Graciela
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2804fa3e24084090b2f572fc810817f0-GIGUINA]; ORA Press
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=18d78505a1a04d2ea01dce130f0d5de8-ORAPress]; Norris, Gary
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc19fae0c7d44332a71e1ff7aa2cefbc-Gary.Norris]; CFSAN OC SRT
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f8a10a0d30a646e5977d8316eeb0b822-CFSAN OC SR]; CFSANEXECSEC
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=468d52748b974fa598d4dfb4a83ab38f-OFVM-CFSAN-]; OC OCC Legal
Requests-Foods Mailbox [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9958fceea93b4dc1aea7b45e60b3225f-OCOCCLegalR]; Beckerman, Peter
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Alexander, Nicholas
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; CORE Senior Leadership
Team [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f9db20a6993a47d49e05807354ebc954-CORE Senior]; CORE Communications
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c135f0a423cf4631bab8155fda87edfc-CORE Commun]; Tobias, Lindsay
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; McDermott, Catherine
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=09adb790c3854fb7a4b11353b41ee618-Catherine.M]; Byerts, Kirsten
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d3d165c657f04e43bd053efb83e96459-Kirsten.Bye]; FDASocialMedia
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d22cede3bcd4b289b6aa1224c00495a-FDASocialMe]; OMA Foods Vet Med
Team [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c4666fd90ccf4a62a772b655706f7b3f-OMA Foods V]; OMA Leadership
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6bede136d65e4c20bd392c18351a87c2-OMA Leaders]; FDASocialMedia
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d22cede3bcd4b289b6aa1224c00495a-FDASocialMe]; CORE Response Team
2 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5645ad676ffa4838a7ae7ff39511b552-CORE Respon]; Lotze, Andrea
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e03cd80247c94486b9c4f4d1a0a9dfaf-Andrea.Lotz]; Assar, Carrie
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=473af4b8efca47f28f476c771ff32395-Carrie.Assa]; Kulas, Megan
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=870ffe8f17ec4b4faa80d94743e2c6e3-Megan.Kulas]; Davis, Marjorie
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b344bd7de4524250ada67247b7c251f1-Marjorie.Da]; Klontz, Karl C
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f034aab9aa2d44d5ab4a6a036be0686b-KKLONTZ]; Pettengill, James
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=75c30e036b21489a94eff12e48d44daa-James.Pette]; Oxenham, Ann
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b682119aebb490b87abe0fc19b0c09d-Ann.Oxenham]; Hollis, Simone

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eea337712468aabb2f6923b1afe47-Simone.Edmo]; Newby, Edette J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2884e947b2394b3da6361941a43edb5e-ENEWBY]; Darlington, Leonora [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6df123a2cf37410ea4e42ae76b372145-Leonora.Dar]; Smoot, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbebf67a5fa842c2bd91085804b2a087-Leslie.Smoo]; Sheehan, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=768cb0855d5f4eedb2e8f999846ce0bd-JSheehan]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Fox, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76205251cf1349c19a87278dc8ce840c-TFOX]; Jasperse, Carie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9fe77657ab4444b9b27100a347228b2-Carolyn.Jas]; Singleton, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b70632897eee4a66a8e6bf7681210a85-Shannon.Chi]

Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Attachments: FDA_Cronobacter_Infant Formula_2.18.2022.pdf

Good afternoon,

An update to our Advisory will be posted shortly to reflect the recall notice from the firm.

Final language is attached and I will provide the link once we are live.

Thanks all,
Corinne

From: Newhart, Corinne
Sent: Thursday, February 17, 2022 5:12 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership

<OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

We are now live:

Advisory: FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) | FDA

CORE Investigation Table: https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks

The PR will be live shortly

Thanks all,
Corinne

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 4:15 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora

<Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

Below is our final language, we are still targeting 5pm posting. I will send the link once we are live.

FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022)

Do not use certain powdered infant formulas produced at Abbott Nutrition's Sturgis, MI facility

The FDA, along with CDC and state and local partners are investigating four consumer complaints of infant illness related to products from Abbott Nutrition's Sturgis, MI facility received from 9/6/2021 to 12/18/2021. All of the cases are reported to have consumed powdered infant formula (IF) produced from Abbott Nutrition's Sturgis, MI facility. These complaints include three reports of *Cronobacter sakazakii* infections and one report of *Salmonella* Newport infection in infants. All four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case.

FDA has initiated an onsite inspection at the facility. Findings to date include several positive *Cronobacter* results from environmental samples taken by FDA, and adverse inspectional observations by FDA investigators. A review of the firm's internal records also indicate environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*.

FDA is issuing this advisory to alert consumers to avoid purchasing or using certain powdered infant formula produced in the Sturgis, MI facility.

This is an ongoing investigation and the firm is working with the FDA to initiate a voluntary recall of potentially affected product. FDA is continuing to investigate and will update this advisory should additional consumer safety information become available.

Recommendation

The FDA is advising consumers not to use Similac (all varieties) or Elecare powdered infant formulas if:

- the first two digits of the code are 22 through 37 and
- the code on the container contains K8, SH, or Z2, and
- the expiration date is 4-1-2022 (APR 2022) or later.

The code is printed on the product packaging near the expiration date (see product image below). Additional information on products made by Abbott Nutrition is available on their website: https://abbottnutrition.com/infant-and-new-mother

Products that do not contain the information listed above are not impacted by this advisory. This advisory does not include liquid formula products. Consumers should continue to use all product not covered by this advisory.

Products made at the Sturgis facility can be found across the United States and were likely exported to other countries as well.

These powdered infant formulas have the potential to be contaminated with *Cronobacter*, a bacterium that can cause severe foodborne illness primarily in infants. *Cronobacter* infections are rare but are especially high risk for newborn infants (see symptoms below).

Parents and caregivers should never dilute infant formula and should not make or feed homemade infant formula to infants.

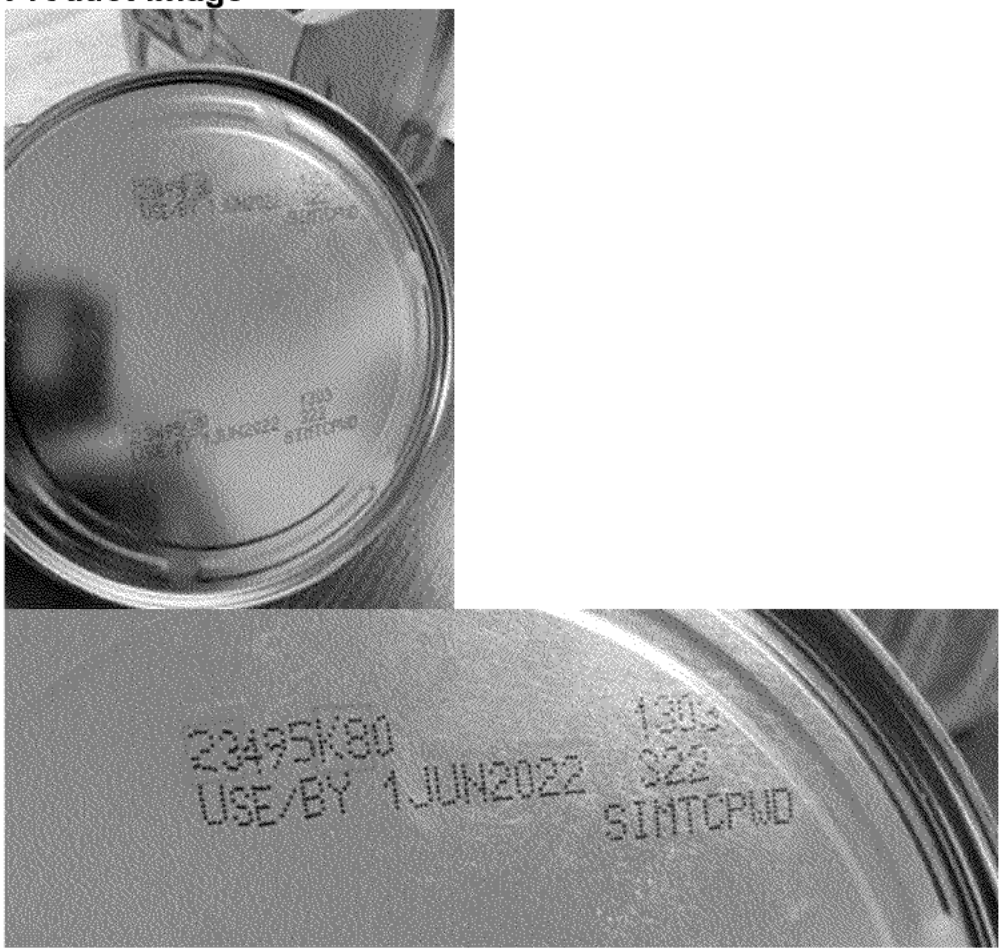
If your regular formula is not available, contact your child's healthcare provider for recommendations on changing feeding practices.

More information on *Cronobacter* and infant formula is available on CDC's website.

Cronobacter bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths, and abnormal movements. Cronobacter infection may also cause bowel damage and may spread through the blood to other parts of the body.

If your child is experiencing any of these symptoms, you should notify your child's healthcare provider and seek medical care for your child immediately. Healthcare providers and health departments are encouraged to report any confirmed cases of *Cronobacter sakazakii* to CDC.

Product Image



Useful Links

- CDC information on *Cronobacter* and infant formula
- What is *Salmonella*?
- Food Safety Tips for Consumers & Retailers During an Outbreak

Case Counts

Total Adverse Events: 4 (3 *Cronobacter*, 1 *Salmonella*)
Hospitalizations: 4
Reported Deaths: 1*
Adverse Event Dates: 9/6/2021 – 12/18/2021
States with Adverse Events: MN (1), OH (1), TX (2)
Product Distribution: Nationwide and International

- Who to Contact

*One death has been reported but has not been confirmed to be solely attributable to *Cronobacter* infection.

Who to Contact

If your child has symptoms you should contact their health care provider to report their symptoms and seek care immediately.

To report a **complaint** or **adverse event** (illness or serious allergic reaction), you can

- Call an FDA Consumer Complaint Coordinator if you wish to speak directly to a person about your problem.
- Complete an electronic Voluntary MedWatch form online.
- Complete a paper Voluntary MedWatch form that can be mailed to FDA.

Visit www.fda.gov/fcic for additional consumer and industry assistance.

Submit Questions Electronically

Get E-mail Updates

Follow Us on Twitter

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 1:16 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone

<Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

Our Advisory and Press Release are now scheduled for 5pm today.

Final text will be provided in advance of posting.

Thank you all,
Corinne

From: Newhart, Corinne
Sent: Wednesday, February 16, 2022 9:03 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OO-OFBA-Congressional-Government <OO-OFBA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Cathy Abi-Khattar <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; OFVM-CFSAN-CVM-OEP <OFVM-CFSAN-CVM-OEP@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

This email is to inform leadership that we will be issuing a new advisory today on the investigation of three consumer complaints of *Cronobacter sakazakaii* infections and one complaint of *Salmonella* Newport infection.

The advisory is in clearance now and we are targeting a release before COB today, to align with the addition of this investigation to the CORE Investigation Table.

Those who need to clear have or will be contacted separately.

If you have any questions or concerns, please let me know. I will share final language with this group in advance of posting and the link once we are live.

Thanks all,
Corinne

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 4/4/2022 10:35:46 AM
To: Douglas Stearn (Douglas.Stearn@fda.hhs.gov) [Douglas.Stearn@fda.hhs.gov]
Subject: Slides
Attachments: HHS briefing on Infant Formula 3_30_22 Final.pptx

Slide 12

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

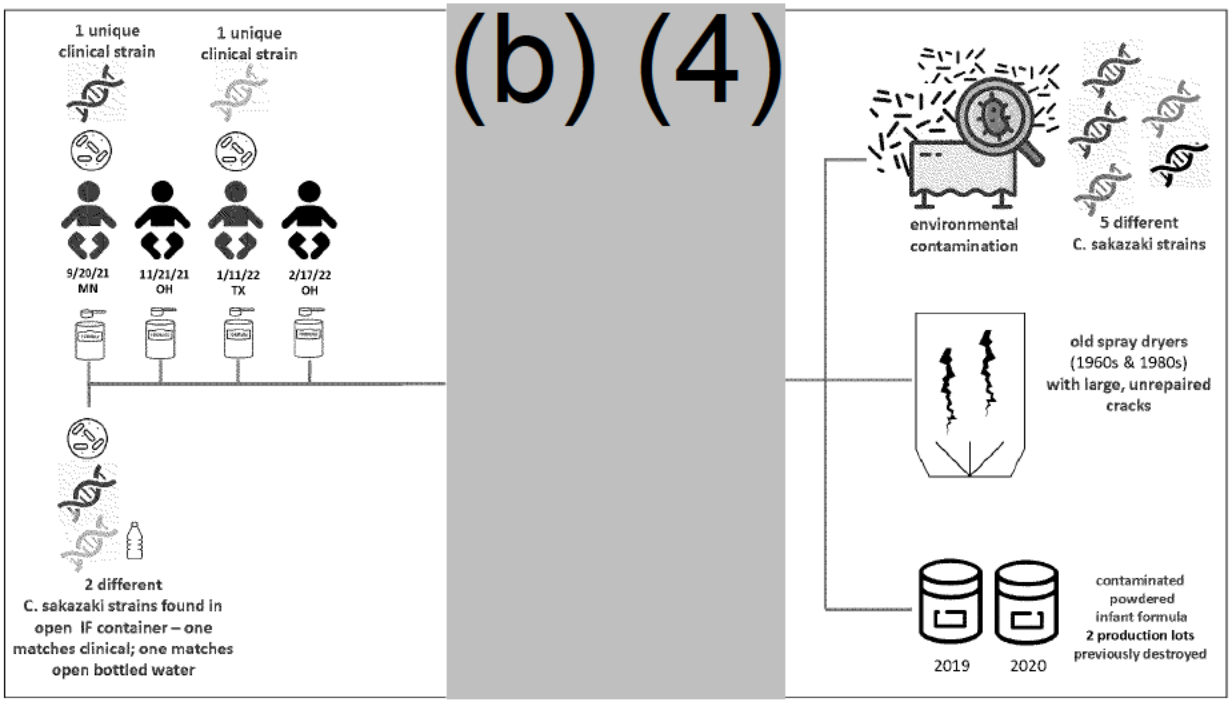
U.S. FOOD & DRUG ADMINISTRATION

HHS briefing: Abbott Nutrition – Sturgis, MI Facility Inspection, Powdered Infant Formula Recall, and Supply Chain

March 31, 2022

Agenda

- Opening remarks
- Discussion of *Cronobacter* cases
- State of the recall and consent decree
- Supply chain
- Congressional Interest & A-19
- Next Steps
- Discussion


1 unique clinical strain
1 unique clinical strain
9/20/21 MN
11/21/21 OH
1/11/22 TX
2/17/22 OH
2 different C. sakazaki strains found in open IF container – one matches clinical; one matches open bottled water
(b) (4)
environmental contamination
5 different C. sakazaki strains
old spray dryers (1960s & 1980s) with large, unrepaired cracks
2019
2020
contaminated powdered infant formula
2 production lots previously destroyed

Current Case Counts and *Cronobacter* Surveillance

- **Cases identified with reported exposure to Sturgis, MI, Abbott Nutrition**
  - Four *Cronobacter* (1 *Salmonella)*
  - All 4 *Cronobacter* cases were hospitalized, including 2 deaths (*Cronobacter* infection may have contributed to the cause of death for both infants)
  - The *Cronobacter* cases were reported 9/20/2021, 12/01/2021, 1/11/2022, and 2/17/2022
  - States with cases: MN (1), TX (1), OH (2)
  - Product Distribution: Nationwide and International
  - Whole Genome Sequencing results

- ***Cronobacter* surveillance**
  - *Cronobacter* infection surveillance is not handled the same way as infection with more common foodborne pathogens, such as *Salmonella* or *E. coli* O157:H7.
  - *Cronobacter* is not nationally notifiable and not reportable, with the exception of MN. There are other mechanisms of reporting.
  - FDA relies on consumer complaints of illness sent to the agency and on health care providers informing FDA directly about infants with *Cronobacter* infections.
  - Analysis from whole genome sequencing (WGS) data performed at CDC is not routinely reported back to states. To date, no outbreaks of *Cronobacter* have been detected using WGS.
  - When single cases of *Cronobacter* are reported, the FDA conducts a thorough review, conducts sampling of products, and initiates inspections as appropriate.
  - FDA collaborates with CDC, which has a detailed questionnaire specifically for *Cronobacter* infections that is often used by state health departments in instances of *Cronobacter sakazakii* infection.

Abbott Nutrition – Sturgis 10-year History

Date of inspection	Inspection type	Classification
9/2021	Surveillance	VAI
9/2019	Surveillance	VAI
9/2018	Surveillance	NAI
9/2017	Surveillance	NAI
9/2016	Surveillance	NAI
3/2016	For-cause/consumer complaint (GI illness)	NAI
9/2015	Surveillance	NAI
6/2014	Surveillance	NAI
12/2013	For-cause/fortifier recall in Canada	NAI
6/2013	Surveillance	NAI
10/2012	For-cause/consumer complaint (foreign object)	NAI
6/2012	Surveillance	NAI

- No action indicated (NAI): no objectionable conditions or practices were found during the inspection
- Voluntary action indicated (VAI): objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action
- Official action indicated (OAI): regulatory and/or administrative actions will be recommended

2022 For-Cause Inspection (12/31/2021 – 3/18/2022)

- **Areas of concern that led to the for-cause inspection**
  - Unusual number of complaints
  - Results from the September 2021 inspection
    - 2 failed lots due to *Cronobacter Sakazakii*
- **January 27, 2022: ORA preannounced inspection for January 31**
  - First attempt to schedule December 30, 2021, for an inspection to begin on January 3, 2022
    - Facility informed ORA of 12 COVID-positive employees
    - Inspection postponed until January 31
  - Facility again informed ORA of COVID-positive employees prior to the start of the current inspection

Current Inspectional Findings and Next Steps

- **March 18: Form 483 issued; observations (deviations from the regulations) includes:**
  1. Failure to maintain process controls that would prevent product from becoming adulterated
  2. Failure to fully investigate all consumer complaints related to *Cronobacter* and *Salmonella*
  3. Failure to ensure that all surfaces that come into contact with powdered infant formula were maintained to protect product from becoming contaminated
     - Environmental sampling results
     - Facilities and equipment
  - Redacted FDA 483s have been posted
- **Voluntary recalls**
  - Initial voluntary recall – February 17 based on 4 consumer complaints, positive samples, knowledge of positive product
    - Calls with Abbott Nutrition – February 14, 15, 16, and 17
  - Expanded voluntary recall – February 28 expanded to an additional lot due to 4th identified case
- **Abbott's current operational status**
- **Next steps**

(b) (5)

Supply Chain Implications and Mitigation Actions

(b) (4), (b) (5)

Congressional Interest in the Infant Formula Recall

- **FDA briefings: General interest in timeline of illnesses, FDA actions, and relevant updates since the recalls began**
  - February 28, 2022: Senate Agriculture Committee / Sen. Stabenow (chair, D-MI); interested in impacts on WIC program
  - March 10, 2022: House E&C majority / Rep. Pallone (chair, D-NJ); joint briefing with CDC
  - March 15, 2022: House Education and Labor majority / Rep. Bobby Scott (chair, D-VA)
  - March 16, 2022: Senate HELP majority / Sen. Murray (D-WA)
  - March 24, 2022: Senate HELP minority / Sen. Burr (R-NC)

- **Congressional interest**
  - Rep. Krishnamoorthi (D-IL, chair, Subcommittee on Economic and Consumer Policy, House Oversight and Reform) sent a letter to FDA requesting timeline information as well as documents and communications about the Abbott recall (see also press statement (3/24/2022)).
  - Rep. DeLauro (D-CT, chair, House Appropriations) sent a letter to HHS OIG requesting an investigation into FDA's actions leading up to the Abbott Nutrition infant formula recall (also see press statement (3/4/2022)).
  - Rep. Stefanik (R-NY) sent a letter to FDA requesting timeline information about the Abbott recall (see also press statement (2/28/2022)).
  - Additional statements/tweets about the Abbott recall and FDA's actions: Sen. Stabenow (D-MI) (2/19/2022); Sens. Murray (D-WA) & Casey (D-PA) (2/25/2022); Sens. Murray (D-WA) & Casey (D-PA) (3/22/2022).

A19: Preventing Shortages of Infant Formula and Certain Medical Foods

- **Background**
  - No law requires manufacturers of infant formula or essential medical foods for patients with inborn errors of metabolism to notify FDA when they become aware of a circumstance that could lead to a shortage.
- **Proposal**
  - FDA has recommended that Congress require manufacturers of infant formula and certain medical formulas to notify FDA of a permanent discontinuance in the manufacture of such food or an interruption that is likely to lead to a meaningful disruption in the supply of such food within 180 prior to the date of discontinuance or disruption.
  - Included in September 2020 COVID legislative package proposal and FDA's FY22 and FY23 CJs
- **Hill interest/engagements to date**
  - April 2020
    - Briefed House E&C and Senate HELP on COVID-19-related food shortages, facility closures; focused on food supply chain and worker safety; included specific talking points on the infant formula/medical foods mandatory shortage reporting request.
  - March 2021
    - Briefed Senate HELP majority on pandemic-related medical product supply chain issues; raised infant formula/medical foods shortage reporting request in this context.
  - February 2022
    - Briefed Senate HELP Subcommittee on Children and Families (chair Sen. Bob Casey (D-PA)), as the committee is currently considering this legislative proposal.

Congressional Interest in Other Infant Formula Topics

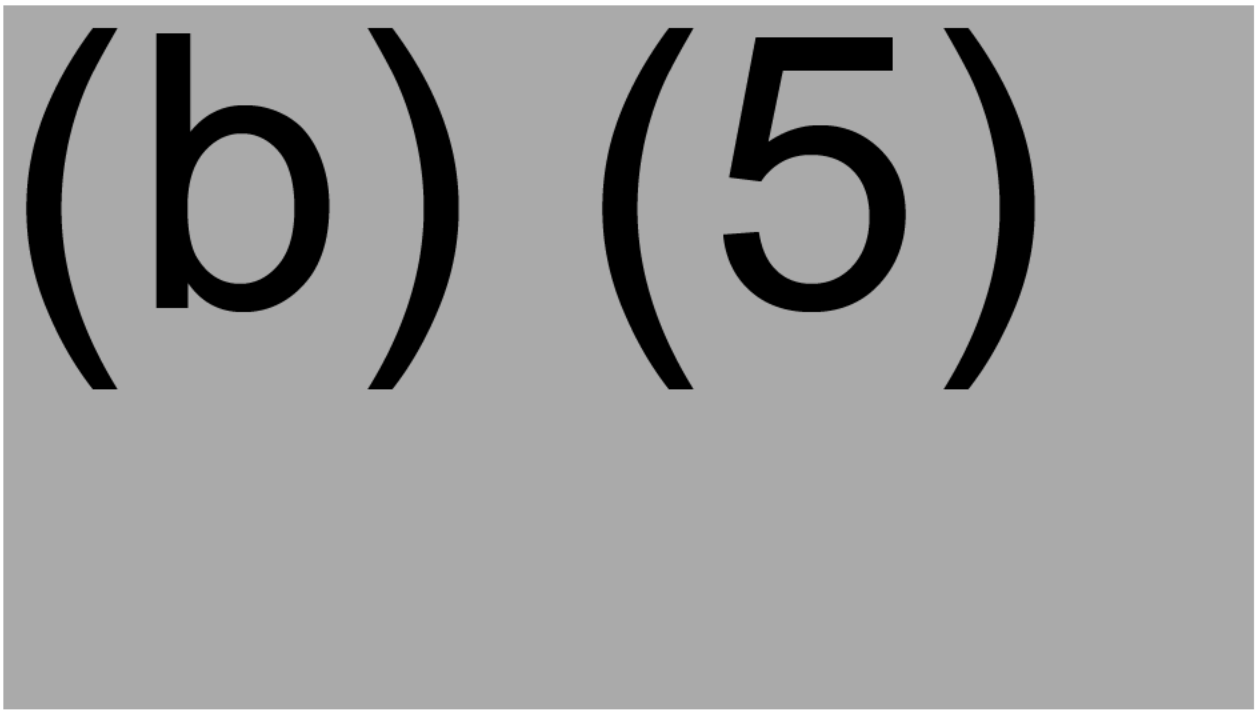
- **FDA's FY22 Infant Formula Budget Initiative**
  - The FY 2022 omnibus funded FDA's request to increase resources for infant formula reviews.
  - The current submission rate exceeds FDA's ability to complete reviews in the 90-day window, which may lead to products being marketed without having been reviewed.
  - The funding will allow FDA to increase its capacity to review infant formula submissions which have greatly increased in number and complexity in recent years.

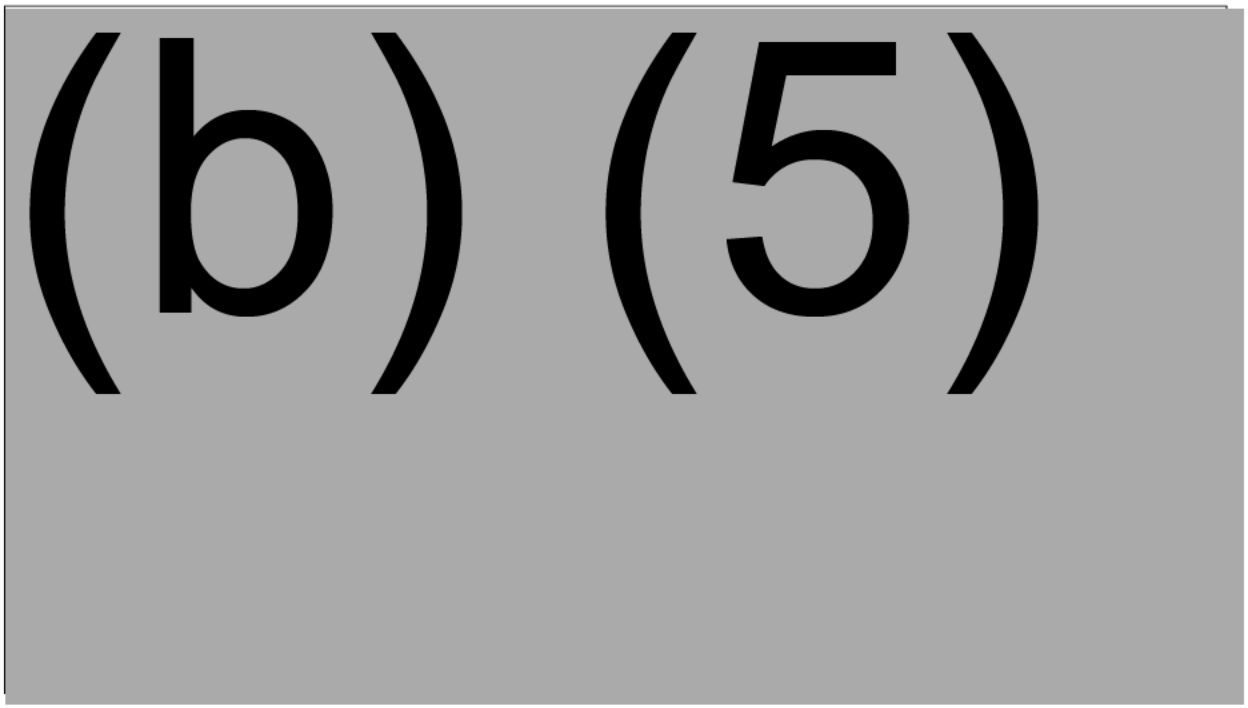
- **Infant Formula Protection ("Use By Dates")**
  - Liquid infant formulas are fat and protein emulsions that separate with time. Additionally, the nutritional quality of infant formula deteriorates with time, and the rate of separation and deterioration of nutritional quality increases at higher temperatures.
  - February 2020: FDA provided technical assistance to Senate HELP majority and House E&C majority on proposed legislation that would deem infant formula adulterated if its "use by" date had passed when sold by retailers (Infant Formula Protection Act of 2021).
  - April 2021: Rep. Meng (D-NY) introduced the Infant Formula Protection Act of 2021.

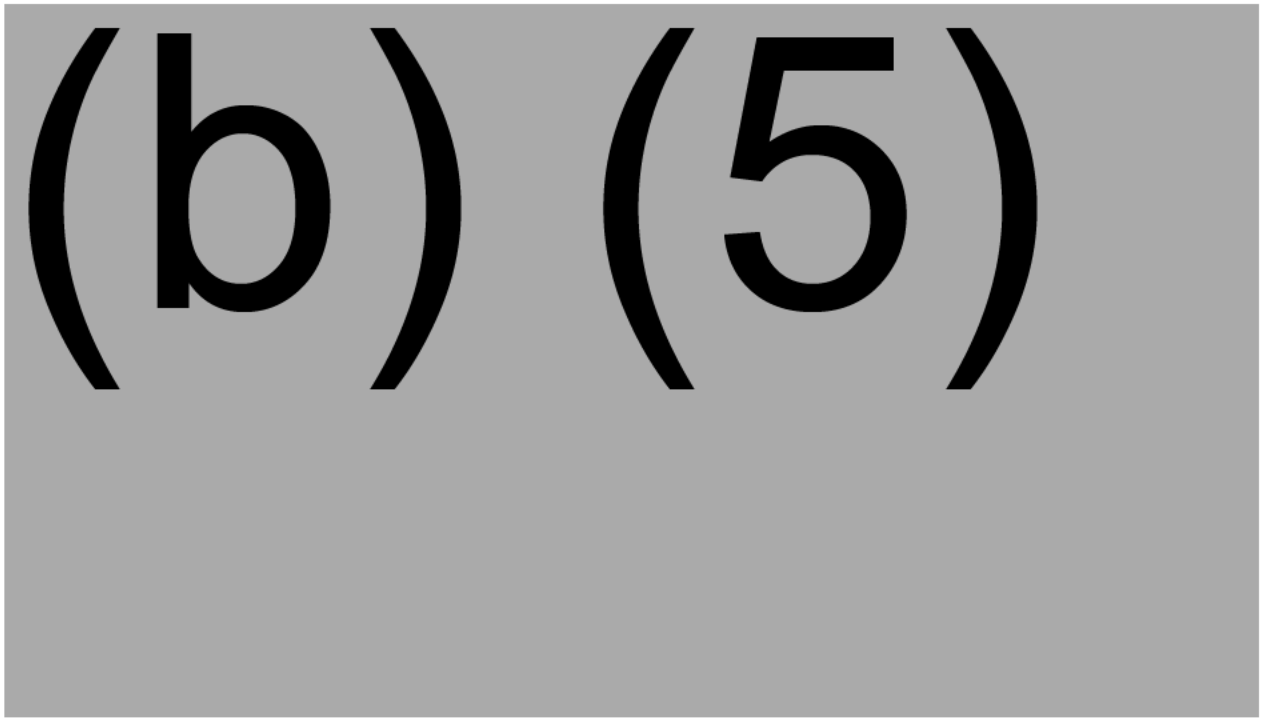
Next steps

(b) (5)

Discussion


(b) (5)


(b) (5)



(b) (5)

From: Kavanaugh, Claudine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E2BB33674F346B89BBEE0B4CCC7B692-CKAVANAU]
Sent: 2/19/2022 8:43:47 PM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]
Subject: RE: Letter Sent by Abbott Nutrition to State WIC Agencies- C. sakazakii, Salmonella Newport/Powdered Infant Formula (sus)/Feb22

Yes, but it may be only for WIC….

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Saturday, February 19, 2022 8:05 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: Letter Sent by Abbott Nutrition to State WIC Agencies- C. sakazakii, Salmonella Newport/Powdered Infant Formula (sus)/Feb22

Isomil is on the list as not affected?

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Saturday, February 19, 2022 7:18 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: Letter Sent by Abbott Nutrition to State WIC Agencies- C. sakazakii, Salmonella Newport/Powdered Infant Formula (sus)/Feb22

This does confirm that soy based formulas aren't affected, we were waiting for that so we can update the PHA. I can see why parents are having a hard time. This info is helpful for us too, the allergenic formula isomil will be in short supply since its only produced at Sturgis along with the Ellecare.

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Saturday, February 19, 2022 7:12 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Re: Letter Sent by Abbott Nutrition to State WIC Agencies- C. sakazakii, Salmonella Newport/Powdered Infant Formula (sus)/Feb22

Agree. That is completely unacceptable.

Get Outlook for iOS

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Saturday, February 19, 2022 7:10:57 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: Letter Sent by Abbott Nutrition to State WIC Agencies- C. sakazakii, Salmonella Newport/Powdered Infant Formula (sus)/Feb22

I included the email-the email had the critical info on the formulas. Abbott is making it hard and that info shouldn't have taken 2 days to produce, very sad.

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Saturday, February 19, 2022 7:06 PM
To: Dean, Stacy - OSEC, Washington, DC <Stacy.Dean@usda.gov>; Chandran, Kumar - OSEC, Washington, DC

<Kumar.Chandran@usda.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: FW: Letter Sent by Abbott Nutrition to State WIC Agencies- C. sakazakii, Salmonella Newport/Powdered Infant Formula (sus)/Feb22

FYI, WIC was waiting for this. Claudine Kavanaugh sent to her WIC contact a minute ago, wanted to share.

From: Kavanaugh, Claudine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E2BB33674F346B89BBEE0B4CCC7B692-CKAVANAU]
Sent: 2/18/2022 5:50:23 PM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]
CC: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]
Subject: Feedback from other IF manufacturers

Hi Susan and Doug,

Just wanted to provide a little more feedback on our communication with the other infant formula manufacturers. They are have been more forthcoming with information than previously. We particularly focused in on the replacement for ellCare which is an amino acid based formula for infants-very specialized but several other companies make a similar product. It does sound like there is some supply of this and the import changes will be helpful. All the companies are looking into how they could ramp things up, but it is taking them time to figure everything out with materials, packaging, stock, and production lines. We have some preliminary info but more will come as they assess. The manufacturers are cognizant of the need but don't want to come across opportunistic or promote their formula w/o parents checking with their pediatrician about the best formula to substitute. We have an idea of Abbotts market share but not what that plant produced of it compared to the others so its hard to say how big of a gap will be. Surprisingly, consumers have not been flooding their consumer lines yet (at least for Nestle and Nutricia)-it will likely be coming. The team is going to get some rest but we are monitoring the situation and hopefully will receive more info from the companies over the weekend. I will be on the Sunday call and available all weekend.

Thanks,

Claudine

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Harris, Stic [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1DB72EDDA1AC46B99F4C4CE832B6D999-ORVILLE.HAR]
Sent: 2/22/2022 5:42:06 PM
To: Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; Klontz, Karl C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f034aab9aa2d44d5ab4a6a036be0686b-KKLONTZ]; Newhart, Corinne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656a525a42e547959efea21ab442bcd6-Corinne.New]; Irvin, Kari [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9fea0d41738d458282b5e0ab147de54d-Kari.Irvin]; Chen, Yi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32b2578cd642d3a946d66742490367-Yi.Chen]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Minor, Travis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9991ec21b8f249d38e65559e7c6e310d-Travis.Mino]
CC: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Lotze, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e03cd80247c94486b9c4f4d1a0a9dfaf-Andrea.Lotz]; Assar, Carrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=473af4b8efca47f28f476c771ff32395-Carrie.Assa]; Bunning, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71fb8547367142d39a9688f2135025dd-VBunning]
Subject: RE: CDC updated their guidance on cronobacter prevention

K.
Just wanted to ask the question.

From: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Sent: Tuesday, February 22, 2022 5:41 PM
To: Harris, Stic <stic.harris@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Chen, Yi <Yi.Chen@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Minor, Travis <Travis.Minor@fda.hhs.gov>
Cc: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Bunning, Kelly <Vincent.Bunning@fda.hhs.gov>
Subject: RE: CDC updated their guidance on cronobacter prevention

My understanding is the current outbreak posting points to this CDC page which is now updated so for now I'd recommend leaving as is (we do have general advice on infant formula on FDA's site but it is not specific to *Cronobacter*)

From: Harris, Stic <stic.harris@fda.hhs.gov>
Sent: Tuesday, February 22, 2022 5:31 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Newhart, Corinne

<Corinne.Newhart@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Chen, Yi <Yi.Chen@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Minor, Travis <Travis.Minor@fda.hhs.gov>
Cc: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Bunning, Kelly <Vincent.Bunning@fda.hhs.gov>
Subject: RE: CDC updated their guidance on cronobacter prevention

Fantastic news.
Should FDA have a similar page to point to? Or are we good simply pointing to CDC's site?

Stic

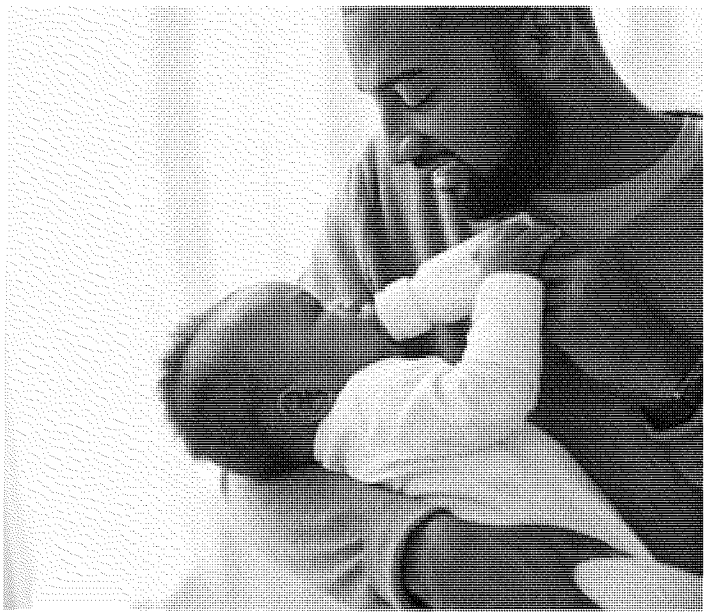
From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Tuesday, February 22, 2022 5:26 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Chen, Yi <Yi.Chen@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Minor, Travis <Travis.Minor@fda.hhs.gov>
Cc: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Bunning, Kelly <Vincent.Bunning@fda.hhs.gov>
Subject: CDC updated their guidance on cronobacter prevention

Hi All,

CDC just updated their guidance on cronobacter prevention to take out the cumbersome advice on temperature and replace it with a specific time to make it more actionable for consumers. Huge thanks to Andrea Lotze for coordinating all the conversations and advice from Yi Chen in ORS! I wish FDA could have clearance this quick on our guidance documents ☺
Link to the advice https://www.cdc.gov/cronobacter/infection-and-infants.html

Pasted below, change is highlighted in yellow.

Prepare and store powdered infant formula safely. Make sure that your formula is not expired or recalled, and that the container is in good condition. Keep powdered formula lids and scoops clean, and close containers of formula as soon as possible. In most cases, it is safe to mix powdered infant formula following manufacturer's instructions. But if your baby is less than 3 months old, was born prematurely, or has a weakened immune system, you may want to take the following extra steps to prepare your formula with hot water (at least 158°F/70°C) to protect against *Cronobacter*:



If your baby is fed with powdered infant formula, there are things you can do to protect your baby from sickness.

1. Clean work surfaces, such as countertops and sinks.
2. Boil water and let it cool for about 5 minutes.
3. Pour into a clean bottle or feeding cup.
4. Add the exact amount of formula listed on the container, and carefully shake the capped bottle rather than stirring the mixture.
5. To use right away, cool the formula to body temperature to ensure it is not too hot before feeding your baby. Run the prepared, capped bottle under cool water or place it into an ice bath. Do not let the cooling water get into the bottle or on the nipple.
6. Before feeding the baby, test the formula's temperature by putting a few drops on the inside of your wrist. It should feel warm, not hot.

Use prepared infant formula within 1 hour from start of feeding and within 2 hours of preparing it. If your baby does not finish the entire bottle of formula, throw away leftover formula

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Kavanaugh, Claudine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E2BB33674F346B89BBEE0B4CCC7B692-CKAVANAU]
Sent: 11/2/2021 3:04:31 PM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]
CC: Carroll, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cb6e346de33480889c94630f0a6ea55-Laura.Carro]
Subject: RE: Infant formula review timelines

Hi Susan,

Before first processing submissions do not have a regulatory time frame but we usually complete these in less than 90 days; sometimes weeks. Sometimes they are something simple like a label change which will go quick or it could be a pkg change/minor formulation change which will take longer but is not to the level of a new submission. The level of BFPs are increasing b/c of the supply chain (per INCA) so that is taking some additional bandwidth of the staff. Hope this helps.

Thanks,

Claudine

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Tuesday, November 2, 2021 2:49 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Cc: Carroll, Laura <Laura.Carroll@fda.hhs.gov>
Subject: Infant formula review timelines

Claudine –

In my TPs for Andi on the infant formula timelines, there is info about the before first processing submissions, which are increasing due to supply chain issues. Given the supply chain issues, do those need to be handled in an expedited fashion? Would they not be under the 180 day timeline? Just want to be sure I understand that.

Thanks,
Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Dooren, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45519CC0BB9F41138B2E95FDFA06E432-JENNIFER.DO]
Sent: 11/16/2021 3:48:20 PM
To: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]
CC: Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Carey, Emily Rose [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21a4cf80bae6477ea95932ffe37b4fc3-EmilyRose.C]; Velez, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf340f58c5cc4b2ab5f59034d5a714d4-Megan.Velez]; Assar, Carrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=473af4b8efca47f28f476c771ff32395-Carrie.Assa]; Lotze, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e03cd80247c94486b9c4f4d1a0a9dfaf-Andrea.Lotz]; Haake, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1915c4e4d49f4540a506d48bfabcb046-Lindsay.Haa]
Subject: RE: [EXTERNAL] CNN news on infant formula supply chain

Thanks – we'll also flag this for the Office of Media Affairs in case they hear from CNN

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Tuesday, November 16, 2021 3:46 PM
To: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Cc: Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Carey, Emily Rose <EmilyRose.Carey@fda.hhs.gov>; Velez, Megan <Megan.Velez@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Haake, Lindsay <Lindsay.Haake@fda.hhs.gov>
Subject: FW: [EXTERNAL] CNN news on infant formula supply chain
Importance: High

Hi Jen and Laura,

Please see the note from INCA below regarding the CNN story on infant formula issues. As I mentioned this morning, part of the challenges with reviewing the 90 day submissions are the competing priorities for reviewing the BFPs which have almost doubled due to more challenges with the supply chain. I wouldn't be surprised if we may be contacted by CNN as well. I will be reaching out to INCA tomorrow to discuss our extension and discuss this issue as well. INCAs message is consistent with what they have been communicating with us, there are challenges with the supply chain but it hasn't impacted the supply. Please reach out if you want to discuss.

Thanks,

Claudine

From: Dockter, Berit <bdockter@infantnutrition.org>
Sent: Tuesday, November 16, 2021 3:14 PM
To: Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>

Cc: Mountford, Mardi <MMountford@kellencompany.com>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: [EXTERNAL] CNN news on infant formula supply chain
Importance: High

Dear Andrea and Carrie,

INCA was contacted by CNN for a news story on infant formula and supply chain challenges. I am bringing to your attention to let you know if you hear anything. Here is the response we sent CNN:

Meeting the needs of the families who rely on infant formula is a top priority for members of the Infant Nutrition Council of America. This is why we want to reassure parents and caregivers that supplies of infant formula are available to meet their needs. Manufacturers are actively working to mitigate the impact of any challenges that may currently be affecting supply chain, transportation and distribution systems around the globe. This includes working with distributors, retailers and state agencies on innovative ways (e.g. direct shipment to stores and prioritizing infant formula shipments) to ensure availability of and continued access to infant formula. It is essential that parents and caregivers obtain infant formula from a safe, reliable source, and they should discuss feeding-related questions with their child's pediatrician.

We will share updates as they arise. Please let us know if you have any questions.

Sincerely,

Berit

Berit Dockter MPP, RD, LD
Scientific & Regulatory Affairs Manager
INFANT NUTRITION COUNCIL OF AMERICA 50 YEARS & COUNTING
1280 National Press Building
529 14th Street, NW
Washington, DC 20045
Direct: 202-207-1112 | Mobile: 928-848-9590
Email: bdockter@infantnutrition.org
Website: www.infantnutrition.org

From: Kavanaugh, Claudine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E2BB33674F346B89BBEE0B4CCC7B692-CKAVANAU]
Sent: 11/16/2021 3:46:14 PM
To: Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]
CC: Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Carey, Emily Rose [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21a4cf80bae6477ea95932ffe37b4fc3-EmilyRose.C]; Velez, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf340f58c5cc4b2ab5f59034d5a714d4-Megan.Velez]; Assar, Carrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=473af4b8efca47f28f476c771ff32395-Carrie.Assa]; Lotze, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e03cd80247c94486b9c4f4d1a0a9dfaf-Andrea.Lotz]; Haake, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1915c4e4d49f4540a506d48bfabcb046-Lindsay.Haa]
Subject: FW: [EXTERNAL] CNN news on infant formula supply chain

Importance: High

Hi Jen and Laura,

Please see the note from INCA below regarding the CNN story on infant formula issues. As I mentioned this morning, part of the challenges with reviewing the 90 day submissions are the competing priorities for reviewing the BFPs which have almost doubled due to more challenges with the supply chain. I wouldn't be surprised if we may be contacted by CNN as well. I will be reaching out to INCA tomorrow to discuss our extension and discuss this issue as well. INCAs message is consistent with what they have been communicating with us, there are challenges with the supply chain but it hasn't impacted the supply. Please reach out if you want to discuss.

Thanks,

Claudine

From: Dockter, Berit <bdockter@infantnutrition.org>
Sent: Tuesday, November 16, 2021 3:14 PM
To: Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>
Cc: Mountford, Mardi <MMountford@kellencompany.com>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: [EXTERNAL] CNN news on infant formula supply chain
Importance: High

Dear Andrea and Carrie,

INCA was contacted by CNN for a news story on infant formula and supply chain challenges. I am bringing to your attention to let you know if you hear anything. Here is the response we sent CNN:

Meeting the needs of the families who rely on infant formula is a top priority for members of the Infant Nutrition Council of America. This is why we want to reassure parents and caregivers that supplies of infant formula are available to meet their needs. Manufacturers are actively working to mitigate the impact of any challenges that may currently be affecting supply chain, transportation and distribution systems around the globe. This includes working with distributors, retailers and state agencies on innovative ways (e.g. direct shipment to stores and prioritizing infant formula shipments) to ensure availability of and continued access to infant formula. It is essential that parents and caregivers obtain infant formula from a safe, reliable source, and they should discuss feeding-related questions with their child's pediatrician.

We will share updates as they arise. Please let us know if you have any questions.

Sincerely,

Berit

Berit Dockter MPP, RD, LD
Scientific & Regulatory Affairs Manager
INFANT NUTRITION COUNCIL OF AMERICA 50 YEARS & COUNTING est. 1970
1280 National Press Building
529 14th Street, NW
Washington, DC 20045
Direct: 202-207-1112 | Mobile: 928-848-9590
Email: bdockter@infantnutrition.org
Website: www.infantnutrition.org

From: Kavanaugh, Claudine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E2BB33674F346B89BBEE0B4CCC7B692-CKAVANAU]
Sent: 11/19/2021 9:56:26 AM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]
CC: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]; Velez, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf340f58c5cc4b2ab5f59034d5a714d4-Megan.Velez]; Carey, Emily Rose [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21a4cf80bae6477ea95932ffe37b4fc3-EmilyRose.C]
Subject: Update on Infant Formula/INCA phone call

Hi All,

I met with INCA this morning to alert them of the additional review time we are adding to any new 90 day infant formula submissions. They were actually supportive b/c they realize we are receiving a lot more Before First Processing submissions (BFPs) in addition to the increased load of the 90 day submissions. We have a larger meeting with INCA scheduled for Dec 3rd , which includes their members, so we will be able to address questions and have further dialogue. They greatly appreciated the reach out. A few tidbits from the call:

-manufacturers are still dealing with supply chain/shipping challenges like every industry but no issues are impacting the production of infant formula
-INCA has been reaching out to the hill to support budget increase; they have called 15 lawmakers already

Please let me know if you have any questions.

Claudine

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Pillsbury, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=962A7ED1A2A24B308CB6CCC3673C53AE-LAURA.PILLS]
Sent: 11/19/2021 12:31:38 PM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]
CC: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Velez, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf340f58c5cc4b2ab5f59034d5a714d4-Megan.Velez]; Carey, Emily Rose [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21a4cf80bae6477ea95932ffe37b4fc3-EmilyRose.C]
Subject: RE: Update on Infant Formula/INCA phone call

Thanks, Claudine.

Jen and I were able to share this update with Lindsay and Kim in the IO on our check-in this AM, so very helpful to have the info.

Have a nice weekend all,

Laura

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Friday, November 19, 2021 10:03 AM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Velez, Megan <Megan.Velez@fda.hhs.gov>; Carey, Emily Rose <EmilyRose.Carey@fda.hhs.gov>
Subject: RE: Update on Infant Formula/INCA phone call

Thanks for that very helpful update.

Best,
Susan

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Friday, November 19, 2021 9:56 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Velez, Megan <Megan.Velez@fda.hhs.gov>; Carey, Emily Rose <EmilyRose.Carey@fda.hhs.gov>
Subject: Update on Infant Formula/INCA phone call

Hi All,

I met with INCA this morning to alert them of the additional review time we are adding to any new 90 day infant formula submissions. They were actually supportive b/c they realize we are receiving a lot more Before First Processing submissions (BFPs) in addition to the increased load of the 90 day submissions. We have a larger meeting with INCA scheduled for Dec 3rd , which includes their members, so we will be able to address questions and have further dialogue. They greatly appreciated the reach out. A few tidbits from the call:

-manufacturers are still dealing with supply chain/shipping challenges like every industry but no issues are impacting the production of infant formula
-INCA has been reaching out to the hill to support budget increase; they have called 15 lawmakers already

Please let me know if you have any questions.

Claudine

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 4/7/2022 7:11:16 AM
To: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Oxenham, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b682119aebb490b87abe0fc19b0c09d-Ann.Oxenham]
Subject: Axios: Families grappling with baby formula shortages

https://www.axios.com/baby-formula-shortages-abbott-nutrition-recall-86ed942c-74d1-48c5-b06b-09a033220547.html

For awareness.

Susan
Get Outlook for iOS

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/23/2022 9:50:46 PM
To: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]
CC: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]
Subject: RE: FOR REVIEW/COMMENT - RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

I glanced through the document; helpful, thanks. As to (b) (5) (b) (5). But if not, (b) (5) (b) (5)? (b) (5)?

Susan

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Wednesday, February 23, 2022 6:27 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: FOR REVIEW/COMMENT - RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Susan/Doug/Leslie,

Here is the current draft of the above document, available at the SP link and also as attachment in case you have trouble accessing. Input from OC and IAS/Doug B has been incorporated. I've retained comment bubble dialogue on a few issues that are not quite resolved and where we'd especially appreciate your thoughts and broader discussion.

Temp shortage Infant Rx - strategy for Abbott recall draft.docx

If you have questions or otherwise need more information, please let us know.

Pat

From: Hansen, Patricia A
Sent: Wednesday, February 23, 2022 1:02 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Sure, Susan.
OC is still inputting and you will see our two offices are in dialogue on a couple of points.
If you need anything else or have questions/comments, pls just give a shout.
Pat

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 4/7/2022 11:33:47 AM
To: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; McKinnon, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd27415bf7ea4a9da98b7b6e6da43ad3-Robin.McKin]
Subject: RE: Not attending today meeting with Adm Levine

We will send your apologies; I support your priorities here.

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Thursday, April 7, 2022 11:04 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McKinnon, Robin <Robin.McKinnon@fda.hhs.gov>
Subject: Not attending today meeting with Adm Levine

Hi Susan and Robin,

I am sorry, I think I have to miss the meeting with Adm Levine today to deal with Infant formula issues. Several issues did come up today and I really feel I need attend these meetings and be 100% present. Send my apologies.

Thanks,

Claudine

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 10/26/2021 1:25:35 PM
To: Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]

agree. And some will impact whole population but infant formula not that case

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 11/5/2021 10:12:07 AM
To: Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

It is on the agenda for JW for Monday. And I am drafting a note to Andi to be sure she knows to give HHS a heads up on infant formula

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 9/28/2021 3:40:07 PM
To: Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]

it was awkward yesterday on the DPC call as Frank used an example of an infant formula facility where we placed a call to them (it was an Abbott plant). He said he personally made the call and it makes a difference. But at the same time I don't know if he is aware that we talk to the INCA group which would include Abbott regularly so talking to the leadership of those groups versus one processing plant - which is the better approach?

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 2/18/2022 2:16:45 PM
To: Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

I cannot see this infant formula call ending at 2:30. ANy chance we can delay the SAMMIES interview until 2:45 or 3? If not I will drop off to take the SAMMIES call

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 2/22/2022 4:01:22 PM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

I am still on infant formula call - I let Sharon know. Wondering if we can delay her to 4:15? Still not sure we will be done then but hope so

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/11/2022 11:40:22 AM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

Just had a long call with Janet on infant formula. Can talk now. Just call me at (b) (6)

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 4/26/2022 12:07:01 PM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

I would leave it on for now...Who knows where we will be on infant formula etc

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/10/2022 3:06:12 PM
To: Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]

Kim mentioned on last call a new request from Senate Dems asking us about infant formula supply chain and authorities...

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/11/2022 11:54:46 AM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

So looking like there will be an AEG call today at 12:30 on infant formula and I keep the 2 with Andi... that is what I know.

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/12/2022 1:10:18 PM
To: Colonius, Tristan [Tristan.Colonius@fda.hhs.gov]

And that group was already underwater doing the infant formula notifications because of the increase in submissions and complexity BEFORE this whole thing started. THat is also why we asked for the 180 day review timeline

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/13/2022 1:48:43 PM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

I am not planning to attend the 4:00 roll out meeting. I told Megan I would review the urgent legislative text she has to submit today on infant formula supply chain at 4.

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/12/2022 6:39:08 PM
To: Velez, Megan [Megan.Velez@fda.hhs.gov]

It is OK with me to keep it moving. We are immersed in infant formula right now and I saw the prior version. Thx for checking!

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/17/2022 10:11:11 AM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

No - I have not looked at the slides. All infant formula right now

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/17/2022 6:46:44 PM
To: Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]

Sorry my daily infant formula call is at 8:40 so I need to be done by then. Does 8:30 work?

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/18/2022 3:26:43 PM
To: Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]

are you listening to this discussion on contracting and if we have exisitng contracts that could help short-term infant formula? Can you ask Matt for that?

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 2/24/2022 3:12:48 PM
To: Carroll, Laura [Laura.Carroll@fda.hhs.gov]

THanks. And feel free to jump in if helpful. I am of course multitasking on infant formula right now

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/4/2022 5:25:58 PM
To: Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]

In the infant formula meeting. Sounds like a briefing mid week on timeline for JW and RMC. JW is specifically interested in how the consumer complaints were addressed. Doug and I discussed (b) (5)
(b) (5) On the call Tara mentioned Politico is pushing CDC for their timeline and trying to find discrepancies with ours so flagging that as well.

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/10/2022 9:32:52 AM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

Welcome back. Conrad is looking for 10-15 mins for a call today. I am waiting for a follow-up infant formula call to land; likely 11:30. Once that has landed then can we schedule Conrad in?

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/3/2022 9:23:49 AM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

No I will drop off; just had 15 mins to continue infant formula

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/10/2022 12:37:19 PM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

I can send now. Been in infant formula calls

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/15/2022 11:33:20 AM
To: Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]

Perhaps we just have a CFSAN meeting then to discuss next steps on infant formula? Doug is back, Steve too given recent ORA findings

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/18/2022 1:41:30 PM
To: Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

Will do. Have not even eaten lunch yet though (infant formula)

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/23/2022 11:37:16 AM
To: Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]

Jen - in today's food safety news, there is an article on infant formula and it includes a statement from Abbott about the WGS findings. Can you make sure OMA is aware that is now out? We may get questions...I know we

(b) (5)

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 3/10/2022 1:42:24 PM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

Natalie - i am still on infant formula issues so not yet attending the ETO meeting. Can you let them know?

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 4/4/2022 10:41:16 AM
To: Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]

Doug is going to talk to you; we still would like to draft the (b) (5) (b) (5) . In an ideal world (b) (5) (b) (5) ? My strong preference is to have CFSAN lead that. Not sure if you know who is leading, or if I should reach out to Erica to offer...

From: Mayne, Susan [Susan.Mayne@fda.hhs.gov]
Sent: 5/11/2022 11:08:15 AM
To: Summers, Tracy S [Tracy.Summers@fda.hhs.gov]; Hageman, Natalie [Natalie.Hageman@fda.hhs.gov]

Let me try Janet first - she wants to speak to me about infant formula

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 9/9/2021 10:41:55 PM
To: diana.bianchi@nih.gov
Subject: Upcoming conference

Hi Diana,

So nice to see your name today. It is great our teams have been working together so closely and I know we are really looking forward to the upcoming meeting on bioactive ingredients. We really need strong science here to help guide FDA's review in this area in relation to infant formula submissions.

I hope you have been doing OK through this pandemic and have been staying well. I have been splitting time behind (b) (6), as most of my work is still done remotely. Do you get back to (b) (6) much?

Looking forward to connecting around the meeting and hope circumstances allow us to see each other in person as well at a future date.

All the best,
Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]
Sent: 9/28/2021 4:26:47 PM
To: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]
Subject: Re: Do you have a few mins for a quick call?

How about 5:05? Will be short. Can call me at +(b) (6) Infant formula supply chain discussion.

Get Outlook for iOS

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Tuesday, September 28, 2021 4:24:24 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: Do you have a few mins for a quick call?

Sure, let me know when you are available.

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Tuesday, September 28, 2021 3:56 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Do you have a few mins for a quick call?

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 9/30/2021 9:58:12 PM
To: Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]
Subject: RE: draft remarks for the National Food Policy Conference (and note about SFPA)

Thanks! I know it is a lot of materials for two initiatives; glad we are getting through them and into clearance. I would rather be busy with good stuff any day than frustrated with lack of movement 😊

From: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Sent: Thursday, September 30, 2021 9:55 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: draft remarks for the National Food Policy Conference (and note about SFPA)

I think this is finally it for materials that will need your review. Attached and in this link are draft remarks for you and Dr. Woodcock – you'll see that a lot of your portion comes from the HFA web page (section in fish advice, infant formula) I don't need careful edits at this stage – just a general impression if you are OK with the split between you and Dr. Woodcock. Her portion is due to Alex her speech writer tomorrow. (End of day is OK) He typically doesn't add much to food content. I don't have any other agenda items for our 8:30 as we talked today so if that time block helps you for this please take it. I need to clarify with Kim and Lindsay tomorrow if or whether Dr. Woodcock will use slides. They initially said a couple colorful slides would be OK but it would be odd to have them up the whole time. I'm told she doesn't use slides that often. (I watched her hand write remarks once just before a Hill hearing even though she had been given TPs and other material and she explained that was how she got it all in her brain just ahead of time)

National Food Policy Conference2021.docx

Separately, Kari Barrett and I are touching base with Brad mid-day tomorrow.

Thanks, Jen

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 10/4/2021 1:18:02 PM
To: Vargas, Ashley J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=251468be085f4f62a0e60b9446018167-HHS-ashley.]; Bremer, Andrew A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc1f0ebd4c6d48bab8bb1360f45342a4-HHS-andrew.]
CC: Bianchi, Diana (NIH/NICHD) [E] [diana.bianchi@nih.gov]
BCC: McKinnon, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd27415bf7ea4a9da98b7b6e6da43ad3-Robin.McKin]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]
Subject: Bioactives workshop

Dear Drs. Vargas and Bremer,

I am writing to express FDA-CFSAN's deep appreciation for your leadership and support of the recent workshop on bioactive ingredients in infant formula. We have received great feedback on the workshop. Congratulations!

As you know and as I mentioned in my opening remarks, as a science-based public health agency, robust science is the basis for our regulatory decision-making. However, as food technology and innovation advance, there can be unanswered questions best addressed by research, such as many of those surrounding the safe use of bioactive ingredients in infant formula. We at FDA are responsible for evaluating the safety of these ingredients and the workshop began an important dialogue with the broader scientific community regarding considerations for a safety assessment framework.

Please accept my congratulations again on the success of the workshop and my most sincere thanks for your support. I am looking forward to ongoing collaboration between our groups!

Warm regards,
Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 10/1/2021 8:24:53 AM
To: Claudine Kavanaugh [Claudine.Kavanaugh@fda.hhs.gov]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Choiniere, Conrad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=053706355e7e41179c63737c416451fb-CChoinie]; Balentine, Douglas [Douglas.Balentine@fda.hhs.gov]; Carroll, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cb6e346de33480889c94630f0a6ea55-Laura.Carro]; McKinnon, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd27415bf7ea4a9da98b7b6e6da43ad3-Robin.McKin]
Subject: FW: [EXTERNAL] Misleading Marketing by Infant Formula Manufacturers

See newsletter below for several interesting bits of info, especially in relation to infants/children.

Laura – noting AHA "voices for healthy kids" initiative.

I understand much of it is more appropriate for FTC.

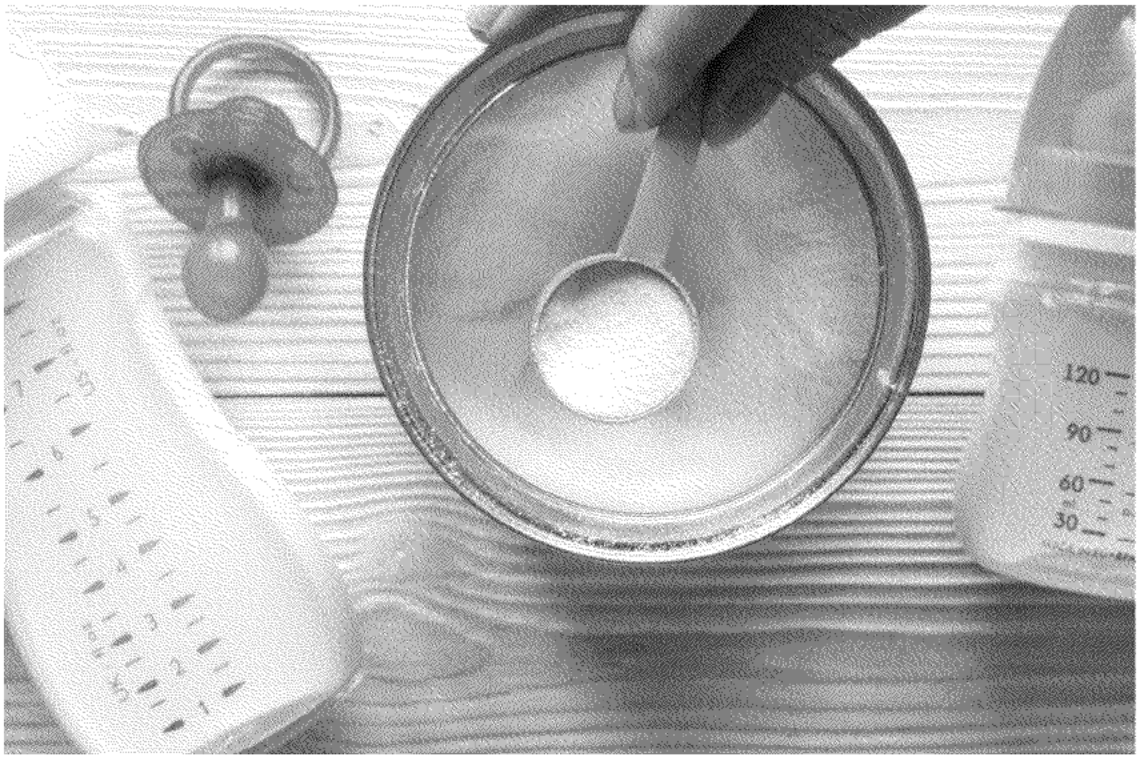
Thanks,
Susan

From: UConn Rudd Center for Food Policy & Obesity <kristin.messina@uconn.edu>
Sent: Friday, October 1, 2021 7:59 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: [EXTERNAL] Misleading Marketing by Infant Formula Manufacturers

UCONN
RUDD CENTER
FOR FOOD POLICY & OBESITY

SEPTEMBER 2021 NEWSLETTER

RECENT PUBLICATIONS



Breastmilk or infant formula? Content analysis of feeding advice on infant formula websites

Researchers found that substantial messaging on baby formula manufacturers' websites encourage infant formula feeding and discourage breastfeeding. Images on the websites also illustrated the benefits of formula—including the ease of feeding, with babies holding their own bottles—while making breastfeeding look difficult and labor intensive. This contradicts the US Surgeon General's recommendations and violates the Code of Marketing of Breast-milk Substitutes.

Published in the *Public Health Nutrition* journal, this study compared information and portrayals of breastfeeding with infant formula feeding on the websites of five infant formula manufacturers. Overall, 44% of the websites mentioned benefits of infant formula while less than 26% mentioned benefits of breastfeeding/milk. The researchers call for stricter regulation of misleading claims by marketers.

Read the full study here.

The Impact of Toddler Milk Claims on Beliefs and Misperceptions: A Randomized Experiment with Parents of Young Children

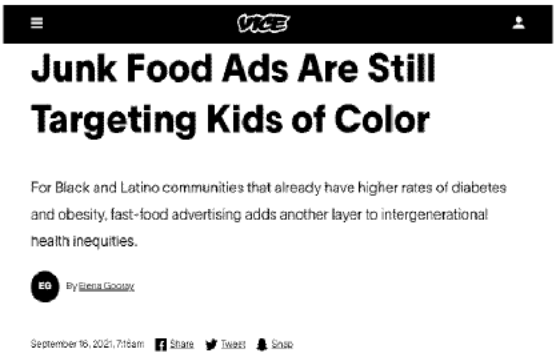
According to WHO's International Code of Marketing, toddler milk, also known as commercial breast milk substitute, should not be directly marketed to consumers. However, misleading claims about brain development or immunity benefits on toddler milk packaging were found to increase parents' intentions of giving toddler milk to their child.

This study, published in the *Journal of the Academy of Nutrition and Dietetics*, also found that brain- and immunity-related claims increased parents' perceived healthfulness of toddler milks, and the belief that pediatricians would recommend the product.

Check out the full study here.

RUDD CENTER IN THE NEWS

ConscienHealth
Featured: Marlene Schwartz, Director
Melissa Jensen, Postdoctoral Fellow

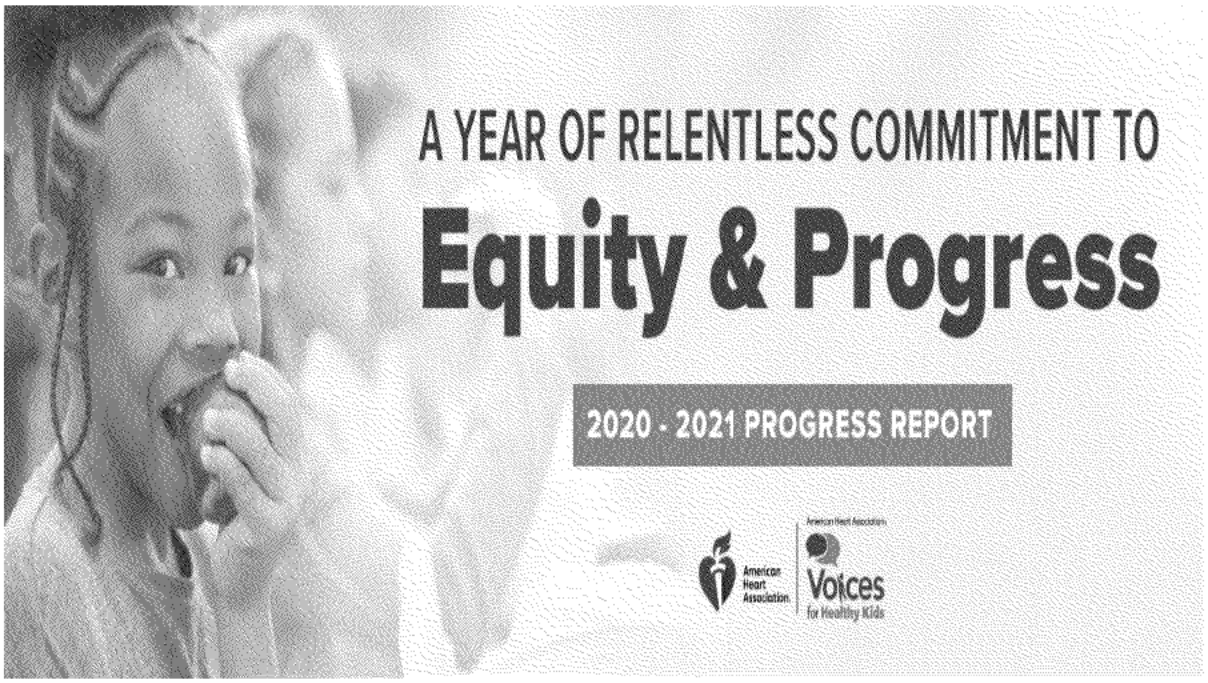


Vice
Featured: UConn Rudd Center

ConscienHealth
Featured: Leah Lessard, Postdoctoral Fellow
Rebecca Puhl, Deputy Director

SciTechDaily
Featured: Jennifer Harris, Senior Research Advisor

WHAT'S SIMMERING WITH OUR FRIENDS?



Voices for Healthy Kids 2020-21 Progress Report
Voices for Healthy Kids

Voices for Healthy Kids, an initiative of the American Heart Association, with support

from the Robert Wood Johnson Foundation, works to amplify the needs and solutions of community leaders who are advocating for changes in policy, systems, and environments in order for children to eat healthy.

The impact of health disparities and structural racism was evident during the COVID-19 pandemic. Their 2020-2021 progress report highlights their work and accomplishments during a particularly challenging year.

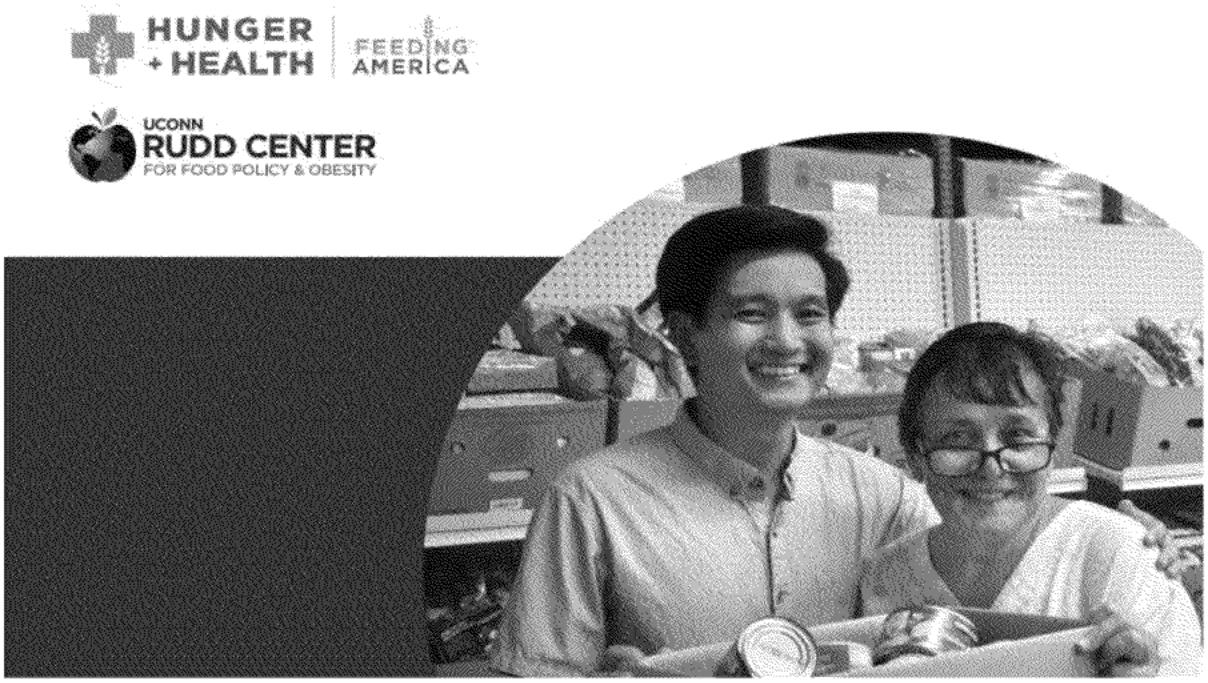
Access the Progress Report here.

NEW RESOURCE: FOOD SYSTEM DATABASE

As part of NOPREN (Nutrition & Obesity Policy Research & Evaluation Network)'s Food Policy Council, Rudd Postdoctoral Fellow Abiodun Atoloye and Rudd Affiliated Faculty Kristen Cooksey-Stowers worked on a Food System Indicators Database that can serve as a resource for groups looking for ways to assess, monitor, and evaluate their local food system. The database includes indicators collected from seven published reports, websites, and academic articles that focus on measuring a variety of elements within the food system.

Access the user guide here.

NEW RESOURCE: NUTRITION IN FOOD BANKING



This month Feeding America released Edition 2 of the Nutrition in Food Banking Toolkit, in which Rudd Director Marlene Schwartz authored a section titled "Improving Nutrition in the Charitable Food System: A Review of the Evidence". This review offers key insights into clients' food needs, nutrition ranking systems, and managing nutrition guideline implementation.

Access the full review here.

FRESH FACES AT RUDD

Brooke Bennett

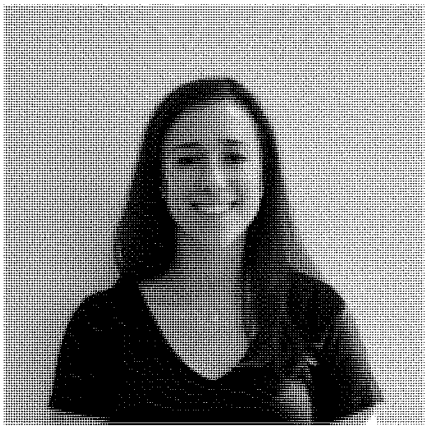
Hometown: Erie, PA

Education: I got my PhD in Clinical Psychology with a dual-specialty in Health Psychology from the University of Hawai'i, Mānoa

Projects at Rudd: I work with Marlene Schwartz and am on the Summer Meals Program team and the Horizon Foundation team.

Research interests: Body image, evidence-based care for eating disorders, and weight stigma. My goal is to find creative, effective ways to improve the health and body image of young adults.

Favorite healthy snack: Peaches



Haley Gershman

Hometown: West Hartford, CT

Education: I got my undergraduate degree in dietetics and my graduate degree in health promotion sciences from the University of Connecticut, Storrs.

Projects at Rudd: I am working with Fran Fleming-Milici and the marketing team.

Research interests: Sugary drink marketing, baby and toddler food marketing, and parent feeding practices. My goal is to work on improving the diets and health of children.

Favorite healthy snack: Apple and peanut butter

Maria Gombi-Vaca

Hometown: Ituiutaba, Minas Gerais, Brazil

Education: I'm a Doctoral Candidate in Public Health at the University of São Paulo School of Medicine. I also have an MPH in Epidemiology from Rio de Janeiro State University.

Projects at Rudd: I work with Caitlin Caspi and Marlene Schwartz, contributing to research on food insecurity and community-based nutrition interventions.

Research interests: The food environment and behavioral factors influencing food choices. My goal is to promote healthier eating practices and health equity.

Favorite healthy snack: Cashew nuts and dried apricot.

Melissa McCann
Hometown: Vernon, CT
Education: I received my undergraduate degree in Neuroscience from Wheaton College, MA and my Master of Public Health from UConn.
Projects at Rudd: I work with Fran Fleming-Milici and Sally Mancini as part of the food marketing team.
Research interests: Unhealthy food and beverage marketing to children, and availability and accessibility of healthy food options in all communities. My goal is to promote equitable food policy and practice to support children growing up healthfully.
Favorite healthy snack: Fruit smoothie

NEWS TO CHEW ON

Big companies are targeting middle income countries to boost ultra-processed food sales
Phys Org

Healthy Food Decisions Can Start at the Grocery Checkout
Inside Science

Could Covid-19 finally end hunger in America?
Politico

Can Accounting for the True Cost of Food Change the Global Food System?
Civil Eats

1 in 5 parents say their kids eat more fast food during the pandemic, pool finds
CNN

Many hurdles for families with food challenges, poll shows
Associated Press

Global Index Shows Top Food and Beverage Companies Must Do More to Fight Malnutrition
Food Tank

Make a Donation

Our mailing address is:
One Constitution Plaza, Ste 600
Hartford, CT 06103

From: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]
Sent: 10/9/2021 10:38:15 AM
To: Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]
Subject: Re: IF Case Study for Supply Chain Report 9-22-21.docx

I agree with your assessment. Frank added in the DPC briefing that his call made a difference (assumed to mean in supply chain continuity but more likely goodwill?)

Get Outlook for iOS

From: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Sent: Saturday, October 9, 2021 10:34:54 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: Re: IF Case Study for Supply Chain Report 9-22-21.docx

Ok, I don't think she'll (b) (5) . I think the key lesson from this from my perspective is we know we can engage with this industry because it is such a small and defined universe. The platform provided additional insights as well but (b) (5) I don't know if we (b) (5) . It looks like Caitlin was looking for someone (David O) to insert that info still in the version you shared.

When they (b) (5)

I personally think the lesson overall on monitoring the industry is that there isn't quite the same organization of the rest of the industry to make the IF engagement practices workable across the board, and that's where the platform provides us better insights for the industry writ large and whether any issues are broader trends or firm/industry-type specific.

Laura

Get Outlook for iOS

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Saturday, October 9, 2021 9:51:57 AM
To: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: Re: IF Case Study for Supply Chain Report 9-22-21.docx

Frank mentioned one phone call to one facility on the DPC briefing. That is what caught me off guard. Can ask Caitlin and will look at your edits.

Susan

Get Outlook for iOS

From: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Sent: Saturday, October 9, 2021 9:19:12 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Sorry for a second email when I know you have too many already – I made some edits to the document for you to consider. These edits would emphasize (b) (5) . I would defer to Claudine if this is (b) (5) , as I've only see the collated results across the calls and nothing specific to infant formula.

From: Pillsbury, Laura
Sent: Saturday, October 9, 2021 9:10 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Susan,

Thanks for sharing this. I think the key for us (b) (5) (b) (5)

Also, this process really has me wondering if (b) (5)) – where we send to Charlotte and Jasmine to facilitate OFPR review. It would not (b) (5)). Happy to discuss this further with you and the other deputies. I'm not sure how often this actually happens, but certainly see a case of saying this is the process to use for documents.

Laura

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, October 7, 2021 2:47 PM
To: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: IF Case Study for Supply Chain Report 9-22-21.docx

---

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Sunday, October 3, 2021 7:11 PM
To: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Cc: Oryang, David <David.Oryang@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Caitlin,

Attached is your draft back with edits/comments from Pat and myself, it was very much a team effort. We provided a lot of feedback/background info in the comment bubbles on the infant formula industry that should be helpful. We also are including a list of a the manufacturing facilities that produce formula for the US, please note not all the manufacturers are in the U.S. You may be surprised by the few number of facilities, as we explain in our comments- (b) (5) . Please reach out if you have questions or want to have a discussion, the infant formula industry is bit of an anomaly since its so small and the product is highly regulated.

Thanks,

Claudine

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Wednesday, September 29, 2021 8:15 AM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Cc: Oryang, David <David.Oryang@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>
Subject: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Claudine,

Here is a very drafty version of what we are trying to pull together for USDA. No need to read in advance – just wanted you to have as we walk you through it a little later this morning.

Thanks,
Caitlin

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 10/24/2021 9:21:59 PM
To: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]
CC: Velez, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf340f58c5cc4b2ab5f59034d5a714d4-Megan.Velez]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]
Subject: RE: infant formula

Thanks for the heads up, Claudine. I can discuss with Leslie, Laura P and Jen at our comms/OEP check in tomorrow.

Best,
Susan

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Friday, October 22, 2021 6:10 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Velez, Megan <Megan.Velez@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: infant formula
Importance: High

Hi Susan and Les,

Pat and I met with the Infant formula team today and they are running on fumes from the heavy work load. The level of 90 day infant formula submissions has remained steady ~20, as soon as they complete a few reviews, more come in. Several of the submissions are extremely complex and technical and take considerable bandwidth. The team is also dealing with an increase in "before first processing" submissions as well, this increase is likely due to the supply chain issues where the infant formula manufacturers have to notify us of changes (e.g. packaging etc…) One of our reviewers is also going to start (b) (6) in a few weeks too!. Unfortunately, we have gotten to a place where we are going to have to request 30 additional days to review the 90 day submissions, this will be a total of 180 days of review- 90 day initial review, 60 day additional review started in Jan 2021 and now 30 additional days. The team knows this isn't a light switch, we need to communicate this with leadership in the agency, change our letters, make a comms/outreach plan etc…before the extension can occur. We want to get the ball rolling on this to help alleviate the team's workload and stress level. I will set up time with Jen/ Laura P/Megan so we can begin to develop a plan for outreach internally and externally in the upcoming weeks. Pat and I are also happy to discuss this with you further, but I don't think the request is a big surprise since we have flagged that it may be coming. We really appreciate the support the Center and Agency leadership have provided in permitting the extensions and giving the staff a more reasonable workload to ensure each submission is adequately reviewed. Please let me know if a meeting is needed.

Best,

Claudine

From: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]
Sent: 10/9/2021 9:51:57 AM
To: Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]
Subject: Re: IF Case Study for Supply Chain Report 9-22-21.docx

Frank mentioned one phone call to one facility on the DPC briefing. That is what caught me off guard. Can ask Caitlin and will look at your edits.

Susan

Get Outlook for iOS

From: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Sent: Saturday, October 9, 2021 9:19:12 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Sorry for a second email when I know you have too many already – I made some edits to the document for you to consider. These edits would (b) (5) . I would defer to Claudine if this is (b) (5) , as I've only see the collated results across the calls and nothing specific to infant formula.

From: Pillsbury, Laura
Sent: Saturday, October 9, 2021 9:10 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Susan,

Thanks for sharing this. I think the key for us (b) (5)

Also, this process really has me wondering if we (b) (5)) – where we send to Charlotte and Jasmine to facilitate OFPR review. It would not (b) (5)). Happy to discuss this further with you and the other deputies. I'm not sure how often this actually happens, but certainly see a case of saying this is the process to use for documents.

Laura

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, October 7, 2021 2:47 PM

To: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: IF Case Study for Supply Chain Report 9-22-21.docx

---

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Sunday, October 3, 2021 7:11 PM
To: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Cc: Oryang, David <David.Oryang@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Caitlin,

Attached is your draft back with edits/comments from Pat and myself, it was very much a team effort. We provided a lot of feedback/background info in the comment bubbles on the infant formula industry that should be helpful. We also are including a list of a the manufacturing facilities that produce formula for the US, please note not all the manufacturers are in the U.S. You may be surprised by the few number of facilities, as we explain in our comments- (b) (5) Please reach out if you have questions or want to have a discussion, the infant formula industry is bit of an anomaly since its so small and the product is highly regulated.

Thanks,

Claudine

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Wednesday, September 29, 2021 8:15 AM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Cc: Oryang, David <David.Oryang@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>
Subject: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Claudine,

Here is a very drafty version of what we are trying to pull together for USDA. No need to read in advance – just wanted you to have as we walk you through it a little later this morning.

Thanks,
Caitlin

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 10/11/2021 9:05:23 PM
To: Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Laura that approach makes sense to me because (b) (5) . Let me know if you would like me to make the request.

From: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Sent: Saturday, October 9, 2021 9:19 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Sorry for a second email when I know you have too many already – I made some edits to the document for you to consider. These edits would (b) (5) . I would defer to Claudine if this is (b) (5) as I've only see the collated results across the calls and nothing specific to infant formula.

From: Pillsbury, Laura
Sent: Saturday, October 9, 2021 9:10 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Susan,

Thanks for sharing this. I think the key for us (b) (5)

Also, this process really has me wondering if we (b) (5)) – where we send to Charlotte and Jasmine to facilitate OFPR review. It would not be (b) (5) . Happy to discuss this further with you and the other deputies. I'm not sure how often this actually happens, but certainly see a case of saying this is the process to use for documents.

Laura

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, October 7, 2021 2:47 PM
To: Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: IF Case Study for Supply Chain Report 9-22-21.docx

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Sunday, October 3, 2021 7:11 PM
To: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Cc: Oryang, David <David.Oryang@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Caitlin,

Attached is your draft back with edits/comments from Pat and myself, it was very much a team effort. We provided a lot of feedback/background info in the comment bubbles on the infant formula industry that should be helpful. We also are including a list of a the manufacturing facilities that produce formula for the US, please note not all the manufacturers are in the U.S. You may be surprised by the few number of facilities, as we explain in our comments- (b) (5) . Please reach out if you have questions or want to have a discussion, the infant formula industry is bit of an anomaly since its so small and the product is highly regulated.

Thanks,

Claudine

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Wednesday, September 29, 2021 8:15 AM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Cc: Oryang, David <David.Oryang@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>
Subject: IF Case Study for Supply Chain Report 9-22-21.docx

Hi Claudine,

Here is a very drafty version of what we are trying to pull together for USDA. No need to read in advance – just wanted you to have as we walk you through it a little later this morning.

Thanks,
Caitlin

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 11/2/2021 2:49:23 PM
To: Claudine Kavanaugh [Claudine.Kavanaugh@fda.hhs.gov]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]
CC: Carroll, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cb6e346de33480889c94630f0a6ea55-Laura.Carro]
Subject: Infant formula review timelines

Claudine –

In my TPs for Andi on the infant formula timelines, there is info about the before first processing submissions, which are increasing due to supply chain issues. Given the supply chain issues, do those need to be handled in an expedited fashion? Would they not be under the 180 day timeline? Just want to be sure I understand that.

Thanks,
Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 11/8/2021 9:44:05 PM
To: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: Infant Formula Review Timeline Challenges

Andi – I updated Dr. Woodcock today on our current situation with infant formula review timeline challenges. We thought it would be good if you could give Steve Cha/HHS a heads up about needing more time (180 days total= 90 day statutory time + 60 day additional time from Jan 2021 + 30 days beginning Nov 19). Here are the details if you need any reminders with key things in yellow.

Thanks,
Susan

- All formulas marketed in the United States must meet federal nutrient requirements and infant formula manufacturers must notify the FDA 90 days prior to marketing a new formula. Among other things, the manufacturer must submit scientific evidence that the formula protein is of sufficient biological quality and that the formula supports normal physical growth when fed as a sole source of nutrition. These submissions are required for infant formulas that are new or for existing formulas undergoing a major change

- The CFSAN ONFL Infant Formula Review Team (IFRT) is responsible for reviewing all the data included in infant formula submissions and strives to complete their reviews within 90 days, the time after which manufacturers can legally market their products. The 90 days is a critical window for FDA to raise questions and resolve issues related to the safety and nutritional adequacy of infant formulas before they are on the market.

ONFL IFRT received an unusually high number of new "90-day" infant formula submissions in late 2020 and early 2021. Due to this increase in submissions, a relatively small staff dedicated to their review, and the significant complexity of many of these submissions, we were unable to complete our reviews of them within 90 days.

- We notified all submitters that we needed an additional 60 days to review, starting in late January 2021.

- The level of infant formula submissions has not subsided since January; we are averaging a case-load of ~twenty "90-day" submissions; this is almost 3 times greater than in previous years. Additionally, we have been finding that many of these submissions are of poor quality and/or include clinical studies that were poorly conducted, which requires additional review efforts.

- Additionally, the IFRT reviews Before First Processing (BFPs) submissions. BFPs are for infant formulas that are not new and are undergoing only minor changes in formulation, processing, or packaging. We are currently receiving twice the number of BFPs to review compared with previous years, some due to the

supply chain challenges during the COVID-19 pandemic. While BFPs do not have a regulatory timeframe, it is nonetheless critical for IFRT to keep up with these submissions.

- Until recently, IFRT has been able to keep up with the "90-day" infant submission reviews with the extended time (60 additional days) but has not been able to keep up with the increased volume of BFPs. However, since mid-October, even the most highly experienced reviewers have starting to experience delays in completing their reviews within the additional timeframe. The stress of this high workload is weighing heavily on the staff
  - Additionally, one staff reviewer will begin (b) (6) for at least three months starting in early November.

- We plan to extend the review time for "90-day" submissions an additional 30 days starting on November 19, 2021 (180 days of total review). The additional review time would only impact **NEW** "90-day" submissions, not those submissions currently under review.
  - For less complex submissions, review may not require the entire additional time. If IFRT completes the review earlier, they will and alert the submitter.

- We have a set number of staff that do these reviews and their training and experience is specialized. We can't easily reallocate staff because of the specialized training needed.

- We have requested additional funding in our FY22 budget and currently this increase is in both the House and Senate versions of the appropriations bill.

- We have also drafted an (b) (5)

- Additional staffing will help alleviate some of our challenges, but the increased complexity of many of the submission also requires additional review time. As an example, infant formula manufacturers are increasingly adding more bioactive components to formula to mimic breast milk; the science surrounding these substances is still evolving, and the submissions need to be thoroughly evaluated for safety.

  - In September 2021, NICHD, FDA, and the NIH Office of Dietary Supplements hosted a virtual workshop, "Exploring the Science Surrounding the Safe Use of Bioactive Ingredients in Infant Formula: Considerations for an Assessment Framework". Experts discussed the state of the science of biologically active human milk components and analogs and the implications for safety assessments when those components and analogs are used in infant formula.
  -

- We plan to reach out to the Infant Nutrition Council of America to alert them of the change in review times. We have briefed them previously and have maintained open communications on our review challenges.

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/22/2022 10:35:08 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: CDC updated their guidance on cronobacter prevention

I did check the updated CDC weblink tonight; note that the top of the page does advise against consuming recalled formula. It is not until later that they have the cronobacter prevention information below (so the concept is when we have strong evidence product may be adulterated, don't consume, but for general prevention against cronobacter boil water etc.)

Just wanted to be sure you were aware of the updates.

Sorry for the numerous emails tonight.

Susan

From: Mayne, Susan
Sent: Tuesday, February 22, 2022 5:40 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: CDC updated their guidance on cronobacter prevention

Here is the link.

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Tuesday, February 22, 2022 5:26 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Chen, Yi <Yi.Chen@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Minor, Travis <Travis.Minor@fda.hhs.gov>
Cc: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Bunning, Kelly <Vincent.Bunning@fda.hhs.gov>
Subject: CDC updated their guidance on cronobacter prevention

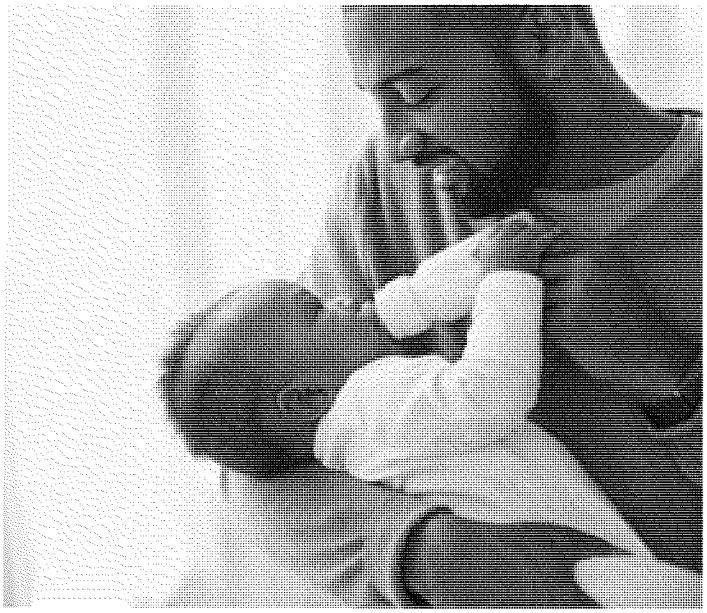
Hi All,

CDC just updated their guidance on cronobacter prevention to take out the cumbersome advice on temperature and replace it with a specific time to make it more actionable for consumers. Huge thanks to Andrea Lotze for coordinating all the conversations and advice from Yi Chen in ORS! I wish FDA could have clearance this quick on our guidance documents ☺
Link to the advice https://www.cdc.gov/cronobacter/infection-and-infants.html

Pasted below, change is highlighted in yellow.

Prepare and store powdered infant formula safely. Make sure that your formula is not expired or recalled, and that the container is in good condition. Keep powdered formula lids and scoops clean, and close containers of formula as soon as possible. In most cases, it is safe to mix powdered infant formula following manufacturer's instructions. But if your baby is less than 3 months old, was born

prematurely, or has a weakened immune system, you may want to take the following extra steps to prepare your formula with hot water (at least 158°F/70°C) to protect against *Cronobacter*:



If your baby is fed with powdered infant formula, there are things you can do to protect your baby from sickness.

1. Clean work surfaces, such as countertops and sinks.
2. Boil water and let it cool for about 5 minutes.
3. Pour into a clean bottle or feeding cup.
4. Add the exact amount of formula listed on the container, and carefully shake the capped bottle rather than stirring the mixture.
5. To use right away, cool the formula to body temperature to ensure it is not too hot before feeding your baby. Run the prepared, capped bottle under cool water or place it into an ice bath. Do not let the cooling water get into the bottle or on the nipple.
6. Before feeding the baby, test the formula's temperature by putting a few drops on the inside of your wrist. It should feel warm, not hot.

Use prepared infant formula within 1 hour from start of feeding and within 2 hours of preparing it. If your baby does not finish the entire bottle of formula, throw away leftover formula

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/23/2022 6:57:40 AM
To: Claudine Kavanaugh [Claudine.Kavanaugh@fda.hhs.gov]; Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]
Subject: Meeting today with USDA, HHS

Julie T is pulling together a meeting today with high level participation from FDA, USDA, HHS. The purpose is to really align on actions on infant formula supply chain, and ensuing communications, as any comms need to be driven by what we learn about supply chains including with subgroups of products.

In advance of this meeting, I have been thinking about how each organization could help, staying true to their missions. For FDA, it seems to me (b) (5) For USDA, as Vilsack is co-chair of the Federal Supply Chain Disruption Task Force, I wonder if (b) (5) . For HHS – I am (b) (5) I am wondering if the(b) (5) :?) Before I float that idea, I wanted your reaction – does this make sense to you? All entities want to help, so trying to channel that into the most productive path rather than having all entities pursuing same action.

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/23/2022 8:28:34 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Frank Yiannas (Frank.Yiannas@fda.hhs.gov) [Frank.Yiannas@fda.hhs.gov]; Boon, Caitlin (Caitlin.Boon@fda.hhs.gov) [Caitlin.Boon@fda.hhs.gov]; Claudine Kavanaugh [Claudine.Kavanaugh@fda.hhs.gov]
Subject: Meeting with USDA and HHS

DRAFT DELIBERATIVE CONFIDENTIAL

In advance of today's meeting, I have been thinking about how each organization could help, staying true to their missions. For FDA, it seems to me (b) (5)). For USDA, I see (b) (5) . Second, Secretary Vilsack is co-chair of the Federal Supply Chain Disruption Task Force--I wonder if (b) (5) For HHS – I am (b) (5)

This is internal FDA brainstorming in advance of the meeting – let me know reactions/concerns.

Julie – can we invite Claudine to listen in; just to be sure we (b) (5) ?

Thanks,

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/23/2022 8:40:05 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Frank Yiannas (Frank.Yiannas@fda.hhs.gov) [Frank.Yiannas@fda.hhs.gov]; 'Boon, Caitlin (Caitlin.Boon@fda.hhs.gov)' [Caitlin.Boon@fda.hhs.gov]; Claudine Kavanaugh [Claudine.Kavanaugh@fda.hhs.gov]
CC: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: Meeting with USDA and HHS

Flag: Follow up

Adding in Tristan and Erica. Should have included.

From: Mayne, Susan
Sent: Wednesday, February 23, 2022 8:29 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Frank Yiannas (Frank.Yiannas@fda.hhs.gov) <Frank.Yiannas@fda.hhs.gov>; Boon, Caitlin (Caitlin.Boon@fda.hhs.gov) <Caitlin.Boon@fda.hhs.gov>; Claudine Kavanaugh <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Meeting with USDA and HHS

DRAFT DELIBERATIVE CONFIDENTIAL

In advance of today's meeting, I have been thinking about how each organization could help, staying true to their missions. For FDA, it seems to me (b) (5) [redacted]). For USDA, I see (b) (5) [redacted], Secretary Vilsack is co-chair of the Federal Supply Chain Disruption Task Force--I wonder if (b) (5) [redacted]. For HHS – I am (b) (5) [redacted]

This is internal FDA brainstorming in advance of the meeting – let me know reactions/concerns.

Julie – can we invite Claudine to listen in; just to be sure we (b) (5) [redacted]?

Thanks,

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/23/2022 12:54:34 PM
To: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]
CC: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]
Subject: RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Pat,

I know it is not vetted but wondering if you can share with me for early awareness? We have a call with USDA/HHS at 2:30 today. Claudine – is that on your calendar yet? I asked them to add you?

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Wednesday, February 23, 2022 12:30 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall
Importance: High

Susan/Doug/Leslie,

This is just a quick fyi to let you know that the multi-tier domestic and input strategy work I outline on yesterday's OFPR infant formula update call is now w/ OC for input/review on quick turnaround. We will loop in Julie M and Doug B, both for situational awareness and input particularly on a broader flex on imports should it prove necessary. On the domestic side, we have something that should help with the Elecare situation – something it looks like you have also brainstormed a bit on a higher level.

We plan to have the document in shape for your review/input later this afternoon. If you have questions, need more information, or would like us to proceed differently, please let us know.

Pat

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/23/2022 10:41:38 AM
To: Frank Yiannas (Frank.Yiannas@fda.hhs.gov) [Frank.Yiannas@fda.hhs.gov]; Boon, Caitlin (Caitlin.Boon@fda.hhs.gov) [Caitlin.Boon@fda.hhs.gov]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
CC: Claudine Kavanaugh [Claudine.Kavanaugh@fda.hhs.gov]
Subject: WaPo article on Elecare....

For awareness and relevant to our meeting today. Jen is looping in Tara and Erica J.

Frank/Caitlin and I discussed this AM the need for metrics on supply chain issues for elecare in particular.

Susan

https://www.washingtonpost.com/lifestyle/2022/02/23/formula-recall-fda-elecare-allergy/

Her son survives on one food. When the FDA recalled it, she put out a plea asking whether anyone had some to spare.

"Nobody asked what's wrong with him. They just asked, 'What can we do?' "

Listen to article
7 min

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/23/2022 1:10:28 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: Claudine

Tristan can we invite Claudine Kavanaugh, who oversees our infant formula and medical foods staff, to the 2:30 meeting with USDA/HHS? Her team is at the interface with USDA so I think it could be helpful.

Thanks!
Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/24/2022 8:39:40 AM
To: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]
CC: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]
Subject: RE: FOR REVIEW/COMMENT - RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Agree – I was thinking (b) (5) .

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Thursday, February 24, 2022 8:32 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: FOR REVIEW/COMMENT - RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Thanks, Susan.
I think the (b) (5) . There will be knowledgeable individual pediatricians out there but many will need a good source of expert opinion and advice. Not sure what you mean when you ask (b) (5) – are you referring to the AAP nutrition committee or some other body?
From ONFL's perspective, we (b) (5) . Happy to discuss further.
Pat

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Wednesday, February 23, 2022 9:51 PM
To: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: FOR REVIEW/COMMENT - RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

I glanced through the document; helpful, thanks. As to (b) (5) . But if not, (b) (5) ?

Susan

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Wednesday, February 23, 2022 6:27 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>

Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: FOR REVIEW/COMMENT - RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Susan/Doug/Leslie,

Here is the current draft of the above document, available at the SP link and also as attachment in case you have trouble accessing. Input from OC and IAS/Doug B has been incorporated. I've retained comment bubble dialogue on a few issues that are not quite resolved and where we'd especially appreciate your thoughts and broader discussion.

Temp shortage Infant Rx - strategy for Abbott recall draft.docx

If you have questions or otherwise need more information, please let us know.

Pat

From: Hansen, Patricia A
Sent: Wednesday, February 23, 2022 1:02 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Sure, Susan.
OC is still inputting and you will see our two offices are in dialogue on a couple of points.
If you need anything else or have questions/comments, pls just give a shout.
Pat

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Wednesday, February 23, 2022 12:55 PM
To: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall

Pat,

I know it is not vetted but wondering if you can share with me for early awareness? We have a call with USDA/HHS at 2:30 today. Claudine – is that on your calendar yet? I asked them to add you?

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Wednesday, February 23, 2022 12:30 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Status Update infant formula supply - Draft doc outlining strategy for mitigating potential infant formula shortages as outfall of the Abbott recall
Importance: High

Susan/Doug/Leslie,

This is just a quick fyi to let you know that the multi-tier domestic and input strategy work I outline on yesterday's OFPR infant formula update call is now w/ OC for input/review on quick turnaround. We will loop in Julie M and Doug B, both for situational awareness and input particularly on a broader flex on imports should it prove necessary. On the domestic side, we have something that should help with the Elecare situation – something it looks like you have also brainstormed a bit on a higher level.

We plan to have the document in shape for your review/input later this afternoon. If you have questions, need more information, or would like us to proceed differently, please let us know.

Pat

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 2/24/2022 3:59:51 PM
To: Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]
CC: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: AAP

For awareness, from AAP (I know Steve Abrams, the pediatrician involved – we worked on DRIs together):

The latest "Ask a Pediatrician" piece is now posted: https://www.healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/What-should-I-know-about-the-infant-formula-recall.aspx

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/1/2022 9:46:45 AM
To: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]
CC: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Oxenham, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b682119aebb490b87abe0fc19b0c09d-Ann.Oxenham]
Subject: RE: FOR REVIEW, TIME-SENSITIVE - Draft doc, strategy for mitigating potential infant formula shortages from Abbott recall

Caitlin is asking this document be expedited and shared ASAP. Leslie/Doug – any concerns sharing with OFPR shortly? If Leslie has provided input I am fine sharing with OFPR for concurrent review. Doug – OK with you?

Susan

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Tuesday, March 1, 2022 7:19 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>
Subject: FOR REVIEW, TIME-SENSITIVE - Draft doc, strategy for mitigating potential infant formula shortages from Abbott recall
Importance: High

Susan/Leslie/Doug,

Here is the current draft of the above document, incorporating input from the last round (including from OC and IAS/Doug B.). We'd appreciate your review as soon as possible as we'd like to move it on and engage w/ OCC.

Temp shortage Infant Rx - strategy for Abbott recall draft.docx

(b) (5)

It's clean copy, not redline, as it was getting fairly messy. I've retained one question of Leslie's along w/ an answer.

As noted, I've also reattached the document w/ the tables on (b) (5) We hadn't heard back from you on that and would appreciate feedback there as well.

If you have questions or otherwise need more information, please let us know.

Pat

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/1/2022 9:33:49 AM
To: Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]
CC: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Oxenham, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b682119aebb490b87abe0fc19b0c09d-Ann.Oxenham]
Subject: RE: FOR REVIEW, TIME-SENSITIVE - Draft doc, strategy for mitigating potential infant formula shortages from Abbott recall

Thanks, Leslie. I started but had to drive to White Oak where I am now. Will hold on editing hold until mid-day.

From: Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Sent: Tuesday, March 1, 2022 9:24 AM
To: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>
Subject: RE: FOR REVIEW, TIME-SENSITIVE - Draft doc, strategy for mitigating potential infant formula shortages from Abbott recall

I am in the doc doing editing and formatting to make it easier to read

---

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Tuesday, March 1, 2022 7:19 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>
Subject: FOR REVIEW, TIME-SENSITIVE - Draft doc, strategy for mitigating potential infant formula shortages from Abbott recall
Importance: High

Susan/Leslie/Doug,

Here is the current draft of the above document, incorporating input from the last round (including from OC and IAS/Doug B.). We'd appreciate your review as soon as possible as we'd like to move it on and engage w/ OCC.

Temp shortage Infant Rx - strategy for Abbott recall draft.docx

(b) (5)

(b) (5)

It's clean copy, not redline, as it was getting fairly messy. I've retained one question of Leslie's along w/ an answer.

As noted, I've also reattached the document w/ the tables on (b) (5) We hadn't heard back from you on that and would appreciate feedback there as well.

If you have questions or otherwise need more information, please let us know.

Pat

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/1/2022 4:31:49 PM
To: Douglas Stearn (Douglas.Stearn@fda.hhs.gov) [Douglas.Stearn@fda.hhs.gov]
Subject: Quick call after 5?

Doug,

I have the OPLIA meeting until 5, then will be leaving White Oak. Can I call you en route to home to discuss infant formula?

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/7/2022 10:04:22 AM
To: Frank Yiannas (Frank.Yiannas@fda.hhs.gov) [Frank.Yiannas@fda.hhs.gov]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]
CC: Morris, Larry (Larry.Morris@fda.hhs.gov) [Larry.Morris@fda.hhs.gov]; Douglas Stearn (Douglas.Stearn@fda.hhs.gov) [Douglas.Stearn@fda.hhs.gov]
Subject: IEC

We do not expect IEC to take 2 hours. Can we set up a separate leadership call to discuss infant formula, say around 11:15 or so? Several ongoing issues it would be good to have alignment on as we begin this week.

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/8/2022 2:02:36 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: Will be joining in a minute; on an infant formula call that is wrapping up

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/8/2022 8:03:59 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Infant formula briefing tomorrow

Janet,

Do you have 5 minutes for a quick call before we get into the infant formula briefing tomorrow afternoon? There is an issue (b) (5) , where I believe your input given your prior experience would be especially valuable. We discussed once before, but I have some updated information to share.

Let me know what might work for you and I will do my best to accommodate.

Thank you,
Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/9/2022 9:41:17 AM
To: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]
Subject: RE: another tidbit from WIC on metabolics

I definitely want them; thanks!

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 9:41 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: FW: another tidbit from WIC on metabolics

Hi Susan,

I am including you on all communications related to metabolics with Caitlin so everyone is receiving the same info esp if Frank starts raising issues that we aren't sharing info. If you would rather not have them, just let me know.

Thanks,

Cluadine

From: Kavanaugh, Claudine
Sent: Wednesday, March 9, 2022 9:36 AM
To: Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Boon, Caitlin (Caitlin.Boon@fda.hhs.gov) <Caitlin.Boon@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: another tidbit from WIC on metabolics

Hi All,

WIC shared another tidbit with me from their discussions with Abbott yesterday. Abbott said off the cuff they have (b) (4) of the metabolic market. WIC asked them to look into it more. I did ask WIC to try to differentiate the share between infant formula and medical foods. There is a larger market of medical food manufacturers out there and I would guess Abbott has less of that but a larger share of infant formula for metabolic disorders since there are really only 3 companies that make infant formulas. I am still amazed at the different info WIC and FDA obtains from Abbott.

Thanks,

Claudine

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/9/2022 11:25:25 AM
To: Hansen, Patricia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c7e582287fa141238f0b0dc6fa623680-PHANSEN]; Kux, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]
CC: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]
Subject: RE: bullets of impacts/examples of what happens if specialty formulas not available

That is a good start. I know you have other examples but gets at the criticality of these products.

Susan

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 10:52 AM
To: Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: bullets of impacts/examples of what happens if specialty formulas not available

Here is a taste of what we're working on.
Please let us know if you need less/more/different.
PH

(b) (5)

From: Hansen, Patricia A
Sent: Wednesday, March 9, 2022 9:35 AM
To: Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn,

Douglas <Douglas.Stearn@fda.hhs.gov>
Subject: RE: bullets of impacts/examples of what happens if specialty formulas not available

We're on it.
Will provide example for a couple of the more striking situations.

From: Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 9:32 AM
To: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>
Subject: RE: bullets of impacts/examples of what happens if specialty formulas not available

Today. Adding Doug and Susan to make comm

From: Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 9:14 AM
To: Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: bullets of impacts/examples of what happens if specialty formulas not available

We had already started work on this – will accelerate ☺ When is next leadership discussion where you expect this to come up?

From: Kux, Leslie <Leslie.Kux@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 9:10 AM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Subject: bullets of impacts/examples of what happens if specialty formulas not available

To make sure Susan has something concrete for leadership discussions. What conditions these formula address and what happens if an infant does not get them short and long term. Let me know if questions

Leslie Kux (she/her) | Deputy Center Director for Regulatory Policy, Nutrition, and Engagement
Office of the Center Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
301-910-9086 (cell)| leslie.kux@fda.hhs.gov

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/10/2022 12:58:30 PM
To: Jennifer Dooren (Jennifer.Dooren@fda.hhs.gov) [Jennifer.Dooren@fda.hhs.gov]
Subject: FW: Outreach to physicians
Attachments: Metabolic talking points 3 10 22.docx

Importance: High

Looping you in for awareness; I am trying to set up a chat with Erica.

From: Mayne, Susan
Sent: Thursday, March 10, 2022 12:47 PM
To: Boon, Caitlin (Caitlin.Boon@fda.hhs.gov) <Caitlin.Boon@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Stic Harris (stic.harris@fda.hhs.gov) <stic.harris@fda.hhs.gov>; Frank Yiannas (Frank.Yiannas@fda.hhs.gov) <Frank.Yiannas@fda.hhs.gov>
Cc: Claudine Kavanaugh <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Outreach to physicians
Importance: High

Ann,

I need to bring you up to speed on some fast-moving work where we are trying to reach out ASAP to physicians/dietitians in relation to infant formula from Abbott. A decision has been made to reach out to physicians/dietitians. I worked on some draft TPs for consideration; ONFL has had input as well. Do any of you (b) (5) (b) (5) ? If you want me to put into SP I can ask Natalie to do so. This would (b) (5) (b) (5) , and I need to reach out to Erica Jefferson as well. I can try to get on a call if you need to discuss Ann –both Stic and Caitlin/Frank and ONFL and the Commissioners office are aware.

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]
Sent: 3/10/2022 1:16:17 PM
To: Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]
Subject: Re: Outreach to physicians

I have not heard back from Erica. I ma

Get Outlook for iOS

From: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Sent: Thursday, March 10, 2022 1:01:39 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: Outreach to physicians

Thanks let me know if you need me to join (I have been point with AAP) I'm also OK not joining

We do need to be prepared (b) (5)

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 10, 2022 12:59 PM
To: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: FW: Outreach to physicians
Importance: High

Looping you in for awareness; I am trying to set up a chat with Erica.

From: Mayne, Susan
Sent: Thursday, March 10, 2022 12:47 PM
To: Boon, Caitlin (Caitlin.Boon@fda.hhs.gov) <Caitlin.Boon@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Stic Harris (stic.harris@fda.hhs.gov) <stic.harris@fda.hhs.gov>; Frank Yiannas (Frank.Yiannas@fda.hhs.gov) <Frank.Yiannas@fda.hhs.gov>
Cc: Claudine Kavanaugh <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Outreach to physicians
Importance: High

Ann,

I need to bring you up to speed on some fast-moving work where we are trying to reach out ASAP to physicians/dietitians in relation to infant formula from Abbott. A decision has been made to reach out to physicians/dietitians. I worked on some draft TPs for consideration; ONFL has had input as well. Do any of you (b) (5) (b) (5) ? If you want me to put into SP I can ask Natalie to do so. This would (b) (5) (b) (5) and I need to reach out to Erica Jefferson as well. I can try to get on a call if you need to discuss Ann –both Stic and Caitlin/Frank and ONFL and the Commissioners office are aware.

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/10/2022 12:56:24 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: infant formula next steps

Importance: High

I need a quick chat. When are you available?

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/10/2022 1:00:43 PM
To: Oxenham, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b682119aebb490b87abe0fc19b0c09d-Ann.Oxenham]
CC: Claudine Kavanaugh [Claudine.Kavanaugh@fda.hhs.gov]
Subject: RE: Outreach to physicians

I can call you in a few minutes; around 1:15 if that works. Which number?

From: Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>
Sent: Thursday, March 10, 2022 12:59 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: Outreach to physicians

Thanks, looking now. If there is any background you want to convey via call I can be available and I'll let you know asap if I have concerns.

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 10, 2022 12:47 PM
To: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Outreach to physicians
Importance: High

Ann,

I need to bring you up to speed on some fast-moving work where we are trying to reach out ASAP to physicians/dietitians in relation to infant formula from Abbott. A decision has been made to reach out to physicians/dietitians. I worked on some draft TPs for consideration; ONFL has had input as well. Do any of you (b) (5) (b) (5) ? If you want me to put into SP I can ask Natalie to do so. This would (b) (5) (b) (5) and I need to reach out to Erica Jefferson as well. I can try to get on a call if you need to discuss Ann –both Stic and Caitlin/Frank and ONFL and the Commissioners office are aware.

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/10/2022 1:19:15 PM
To: Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]
Subject: RE: Outreach to physicians

Can I call you in a bit? I need to get on a call with Ann right now. What works?

From: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Sent: Thursday, March 10, 2022 1:02 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: Outreach to physicians

Thanks let me know if you need me to join (I have been point with AAP) I'm also OK not joining

We do need to be prepared (b) (5)

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 10, 2022 12:59 PM
To: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: FW: Outreach to physicians
Importance: High

Looping you in for awareness; I am trying to set up a chat with Erica.

From: Mayne, Susan
Sent: Thursday, March 10, 2022 12:47 PM
To: Boon, Caitlin (Caitlin.Boon@fda.hhs.gov) <Caitlin.Boon@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Stic Harris (stic.harris@fda.hhs.gov) <stic.harris@fda.hhs.gov>; Frank Yiannas (Frank.Yiannas@fda.hhs.gov) <Frank.Yiannas@fda.hhs.gov>
Cc: Claudine Kavanaugh <Claudine.Kavanaugh@fda.hhs.gov>
Subject: Outreach to physicians
Importance: High

Ann,

I need to bring you up to speed on some fast-moving work where we are trying to reach out ASAP to physicians/dietitians in relation to infant formula from Abbott. A decision has been made to reach out to physicians/dietitians. I worked on some draft TPs for consideration; ONFL has had input as well. Do any of you (b) (5) (b) (5) ? If you want me to put into SP I can ask Natalie to do so. This would (b) (5) (b) (5) and I need to reach out to Erica Jefferson as well. I can try to get on a call if you need to discuss Ann –both Stic and Caitlin/Frank and ONFL and the Commissioners office are aware.

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/10/2022 2:52:43 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: Follow-up

Hi Erica,

I had another follow-up question for you that came from something you shared in the meeting we had with Dr. Califf to discuss infant formula. Less time sensitive than my earlier reach out today, but still would like to follow-up on that. I am free after 4 today, or if you are having a very busy day, can wait until a later date in the near future.

Thanks,
Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/10/2022 6:34:06 PM
To: Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]
Subject: RE: outreach - comms

In red. Do we need to (b) (5) ?

From: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Sent: Thursday, March 10, 2022 6:28 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: outreach - comms

Marrying the two ideas - and knowing others will edit so perhaps better to offer more at the outset

(b) (5)

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 10, 2022 6:12 PM
To: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Subject: RE: outreach - comms

A slightly different take on your edits Jen – you are the comms expert but offering options.

(b) (5)

From: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Sent: Thursday, March 10, 2022 5:58 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: RE: outreach - comms

My feedback in red below but this is what I'm working on from the cleared TPS – OMA asked (b) (5) so this is my first stab in red – I can also put this into Share point – our goal is to (b) (5) (b) (5) (we were going to hold off engaging the larger group until tomorrow am)

(b) (5)

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Thursday, March 10, 2022 5:52 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: RE: outreach

See below, I am drafting a bigger email with more details….

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 10, 2022 5:49 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: RE: outreach

Thanks Claudine. I just got off the phone with Dr. Woodcock. We discussed next steps/loose ends:

(b) (5)

Thank you!

Susan

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Thursday, March 10, 2022 3:23 PM
To: Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: outreach

TPs are cleared and my folks are starting to make calls. I will send a summary of reach outs; reactions when they are complete.

Claudine Kavanaugh, PhD, MPH, RD

Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/10/2022 7:48:43 PM
To: Hageman, Natalie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc1156d328194292a3616c05c312e1f7-Natalie.Hag]; McKinnon, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd27415bf7ea4a9da98b7b6e6da43ad3-Robin.McKin]; Summers, Tracy S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d149bd080a243e2ae15ebdec8d15551-TSUMMERS]
Subject: RE: Call with Dr. Frieden

Makes sense. He will understand from his time at CDC. He can know I have to drop and Robin you can wrap up if needed.

Thanks!
Susan

From: Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>
Sent: Thursday, March 10, 2022 7:46 PM
To: McKinnon, Robin <Robin.McKinnon@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>
Subject: RE: Call with Dr. Frieden

I can reach out to his office first thing in the morning.

From: McKinnon, Robin <Robin.McKinnon@fda.hhs.gov>
Sent: Thursday, March 10, 2022 7:42 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>
Subject: Re: Call with Dr. Frieden

I don't have a preference Susan. You could let him know at the beginning that you will will have to drop after 30 mins but that I can stay on for a few minutes if needed. I am sure he is most interested in dialogue with you. But offering a few more mins may provide flexibility to wrap up the conversation if needed.

Robin

Get Outlook for iOS

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 10, 2022 7:25:47 PM
To: Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; McKinnon, Robin <Robin.McKinnon@fda.hhs.gov>
Subject: Call with Dr. Frieden

As Natalie is aware, I now have an infant formula call scheduled that conflicts with the last 15 minutes of the Frieden call. Can we shorten that call to 30 mins? Or have Robin stay on after I drop? Robin – do you have a preference?

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood