All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	09-Jan-2023	CTU Received Date	09-Jan-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)		

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☑ Noticed a problem with the quality of the product ☑ Had problems after switching from one product maker to another maker
	Date the problem occurred	08-Jan-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I recently started to give my baby the Similac 360 Total Care 8oz ready-to-use formula besides my Enfamil ones, but I noticed multiple times of her dark green watery stools which look like diarrhea very much, and I could hear the diarrhea-like sound in her belly shortly after consuming the formula. I never found this problem after using the Enfamil Nueropro ready-to-use formula in any size. And since the use of the Similac ones, my baby seems to have become tempered, she won't eat quietly as she used to be, no matter bottles or breast milk. I suspect that there are quality issue with these 8oz packagings.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Similac 360 Total Care Infant Formula, with 5 HMO Prebiotics		
Name of the company that makes (or compounds) the product	Abbott		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Yes		

Drug Therapy 1 of 1

Expiration date	01-May-2023		
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Date the person reduced dose of the product			

	Give best estimate of duration	2 Month
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	Unspecified
	Sex	Female
	Gender	Not selected
	Please Specify Other Gender	
	Age (specify unit of time for age)	3 Month(s)
	Date of Birth	
	Weight	5.8 kg
	Ethnicity (Choose only one)	
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

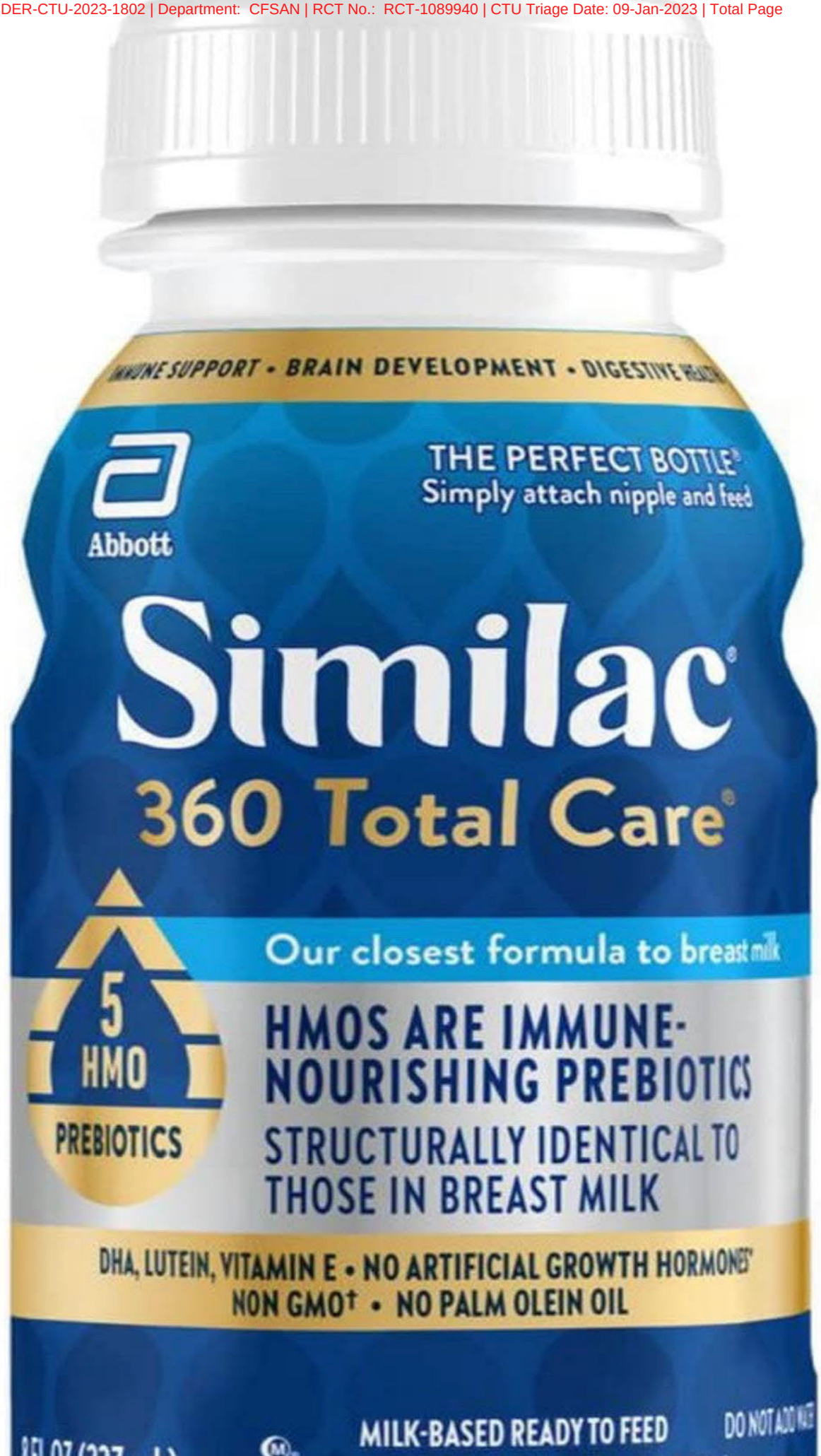
List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	09-Jan-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	


IMMUNE SUPPORT • BRAIN DEVELOPMENT • DIGESTIVE
Abbott
THE PERFECT BOTTLE®
Simply attach nipple and feed
Similac®
360 Total Care®
Our closest formula to breast milk
5 HMO PREBIOTICS
HMOS ARE IMMUNE-NOURISHING PREBIOTICS
STRUCTURALLY IDENTICAL TO THOSE IN BREAST MILK
DHA, LUTEIN, VITAMIN E • NO ARTIFICIAL GROWTH HORMONES
NON GMO† • NO PALM OLEIN OIL
MILK-BASED READY TO FEED
DO NOT ADD

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	07-Feb-2023	CTU Received Date	07-Feb-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)		

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	27-Jan-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

After consuming Similac soy isomorphic infant formula, my 10 month old baby girl developed a fever of 104 that lasted about 2 days. Her symptoms of crying, fussiness, stuffy nose and possibly sore throat continued for an additional two days. She then developed loose bowel movements that have been consistent for the seventh day. Due to diarrhea, baby has developed a diaper rash resulting in red and swollen skin on the labia of the vaginia and sore butt hole. The lot numbers for the Similac Soy(pink can) powder are 45445RE 250 with a use by date of 1APR2024 and 43629RE 190 with a use by date of 1FEB2024. The cans were purchased at a Food Lion in (b) (6).

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Similac Soy Isomil		
Name of the company that makes (or compounds) the product	Abbott		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	3 scoops G gram(s)	If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	01-Feb-2024		
Lot number	43629RE		
Dosage Form			
Quantity		If Other	
Frequency	Every 4 hours	If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product	27-Jan-2023		
Date the person stopped taking or using the product	07-Feb-2023		
Date the person reduced dose of the product			

	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Infant formula as supplemental nutrition

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Age (specify unit of time for age)	10 Month(s)
	Date of Birth	
	Weight	6.3 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ White ☑ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

Cows milk allergy

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

Low percentile of height, weight and head circumference compared to babies in same age group.

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Vitamin D

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	07-Feb-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	


45445RE 250
USE/BY 1APR2024
1902 ISOPWD
45445RE 250
USE/BY 1APR2024
1902 ISOPWD
43629RE 190
USE/BY 1FEB2024
1429 ISOPWD
43629RE 190
USE/BY 1FEB2024
1429 ISOPWD

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	26-Feb-2023	CTU Received Date	26-Feb-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	22-Feb-2023
	Serious	No
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

After every time Feeding my 11 month old similar sensitive formula he has been consistently throwing up at 1st. We thought it was the stomach virus but now we believe it's not. We have tried 2 seperate cans that we bought this month in February and he only vomits up the formula, noting else we give him.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Similac sensitive		
Name of the company that makes (or compounds) the product	Abbott		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Yes		

Drug Therapy 1 of 1

Expiration date	01-Jul-2024		
Lot number			
Dosage Form			
Quantity		If Other	
Frequency	Other	If Other	Every 3 hours
How was it taken or used		If Other	
Date the person first started taking or using the product	15-Feb-2023		
Date the person stopped taking or using the product	26-Feb-2023		
Date the person reduced dose of the product			

	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	11 month old infant

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Female
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Age (specify unit of time for age)	11 Month(s)
	Date of Birth	
	Weight	
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☑ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

one

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

No n e

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

None

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	PA
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	26-Feb-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


USE BY 1 JUL 2024
SSENPUJD

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	31-Mar-2023	CTU Received Date	31-Mar-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☐ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☑ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	30-Mar-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My 1 year old had a high lead test. We got some at home test kits and his formula container showed positive for lead

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD TEST	Test Date	19-Mar-2023
Test Result	13	Test Unit	UNITS

Low Test Range	0	High Test Range	20	
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Similac advance		
Name of the company that makes (or compounds) the product	Abbott nutrition		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	01-Dec-2024			
Lot number				
Dosage Form				
Quantity	Other	If Other	4 Scoops	
Frequency	Every 4 hours	If Other		
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	19-Mar-2022			

	Date the person stopped taking or using the product	20-Mar-2023
	Date the person reduced dose of the product	
	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Baby formula

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Male
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Age (specify unit of time for age)	1 Year(s)
	Date of Birth	
	Weight	12.6 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander

	☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	MD
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	31-Mar-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	22-Apr-2023	CTU Received Date	22-Apr-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☑ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	21-Apr-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

First time using this formula today. Made my 8 month old (former 29week premature) son 2 bottles earlier in the day and when making his 3rd bottle I stopped when I saw a bug in the formula. I picked it out and placed it on the rim and documented with pictures. Approx 18hrs later, my son now has a fever.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Similac Soy Isomil powder		
Name of the company that makes (or compounds) the product	Abbott		
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	01-Jul-2024			
Lot number	48810RE			
Dosage Form				
Quantity	Other	If Other	1 Can	
Frequency	As needed	If Other		
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product				
Date the person stopped taking or using the product				
Date the person reduced dose of the product				

Give best estimate of duration	6 Hour
Is therapy still on-going?	Yes

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Nutritional Formula for infants with GI upset

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b) (6)
Weight	8.9415 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Prematurity, reflux, constipation, feeding problem

Please list all allergies (such as to drugs, foods, pollen or others)

N/A

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

8 month old, however was born at 29 weeks and is currently developmentally and physically screened and treated as a current 5.5month old.

List all current prescription medications and medical devices being used.

Lactulose 10g/15mL - 17 mL twice a day, mixed in with formula bottle

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

N/a

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	TX
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	22-Apr-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


NO PALM OLEIN OIL
Similac®
SOY ISOMIL®


NO PALM OLEIN OIL
Similac
SOY ISOMIL


USE BY JUL2024
USE BY JUL2024

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	04-Aug-2023	CTU Received Date	04-Aug-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)			

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☐ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☑ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	02-Aug-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Using elecare formula for our 10 week old daughter. Found a piece of what I believe to be nitrile glove in the container. Immediately stopped using elecare formula from that can. We then called and reported our finding to elecare (Abbott).

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Food/Medical food
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Elecare
Name of the company that makes (or compounds) the product	Abbott
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar
Strength	If Other
NDC number	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No
Did the problem return if the person started taking or using the product again?	Doesn't Apply

Drug Therapy 1 of 1

Expiration date	01-Feb-2025		
Lot number	49167G30		
Dosage Form			
Quantity	Other	If Other	4 Ounce(s)
Frequency	Every 4 hours	If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product	31-Jul-2023		
Date the person stopped taking or using the product	02-Aug-2023		
Date the person reduced dose of the product			

Give best estimate of duration	
Is therapy still on-going?	Yes

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Breast milk supplement

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	10 Week(s)
Date of Birth	
Weight	5.625 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

Milk and Soy

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

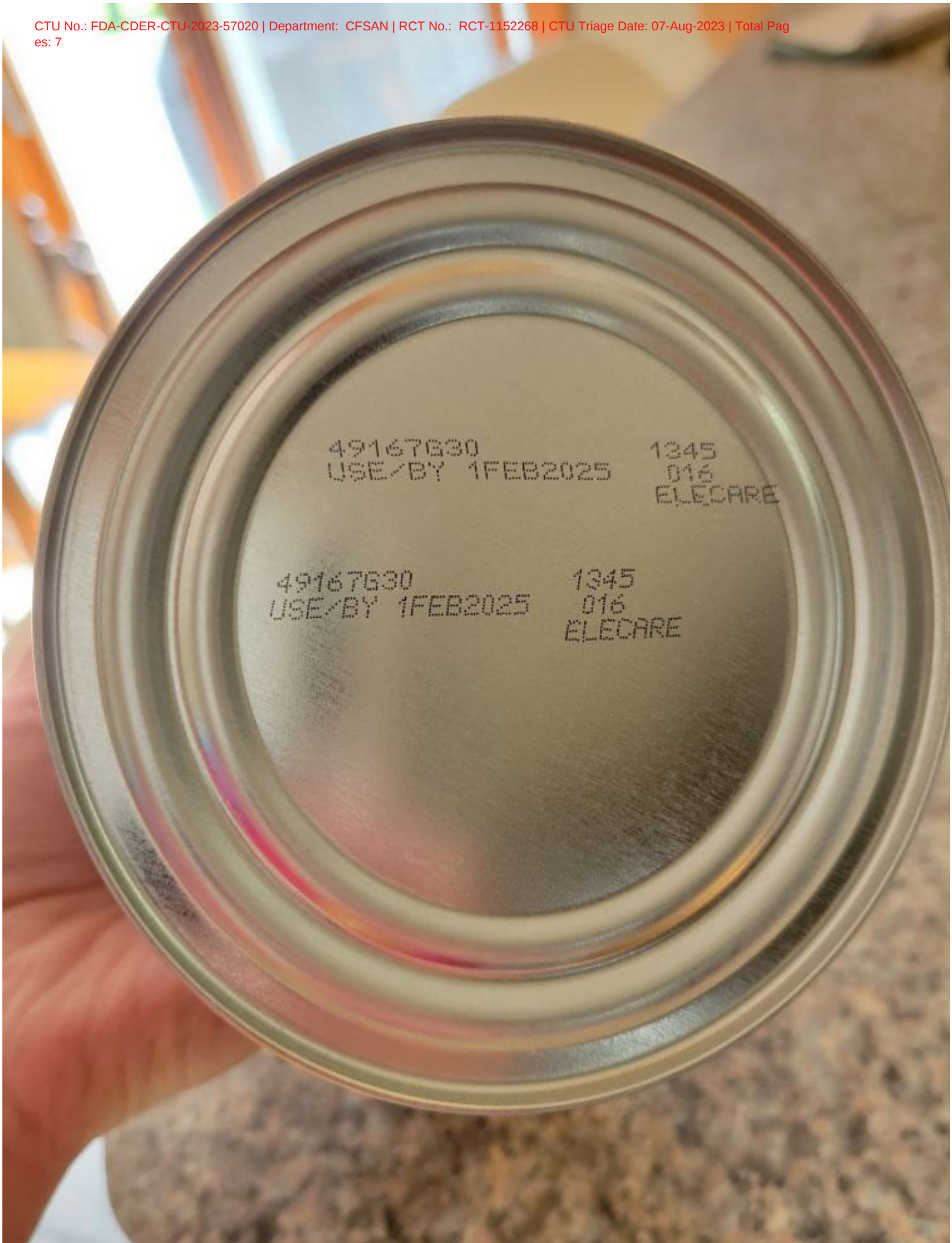
List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	
Number/Street	
City	
State/Province	NY
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	
Email address	
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	04-Aug-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


49167G30
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1345
016
ELECARE
49167G30
USE/BY 1FEB2025
1345
016
ELECARE

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	14-Aug-2023	CTU Received Date	14-Aug-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	04-Aug-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☑ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

5 month old infant became sick with fever, diarrhea. Went to ER after 7 days of illness and tested positive for salmonella. Potentially linked to powdered Similac 360 formula. Required hospitalization and IV antibiotics due to infection in bloodstream. No other sick contacts in household with salmonella.

Relevant Test/Laboratory Data 1 of 2

	Test Name	BLOOD CULTURES	Test Date	10-Aug-2023
	Test Result	Salmonella positive, gram negative rods	Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Relevant Test/Laboratory Data 2 of 2

Test Name	CSF CULTURE WHITE COUNT	Test Date	11-Aug-2023	
Test Result	13	Test Unit	MICROGRAMS PER LITRE	
Low Test Range	0	High Test Range	5	
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Similac 360		
Name of the company that makes (or compounds) the product	Abbott		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	01-May-2025
Lot number	52593H40
Dosage Form	

	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product	26-Jul-2023			
	Date the person stopped taking or using the product	10-Aug-2023			
	Date the person reduced dose of the product				
	Give best estimate of duration				
	Is therapy still on-going?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Baby formula

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Age (specify unit of time for age)	

Date of Birth	(b) (6)
Weight	6.3 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

PFO

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

N/A

List all current prescription medications and medical devices being used.

N/A

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

N/A

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)

	State/Province	MD	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	14-Aug-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

040A0180
P8
HDPE

USE BY DATE ON CONTAINER • USE AS DIRECTED BY A DOCTOR

Directions for Preparation and Use

Your baby's health depends on carefully following these directions. Proper hygiene, handling, and storage are important when preparing infant formula. Failure to follow these directions could result in severe harm. Ask your baby's doctor if you need to use cooled, boiled water for mixing and if you need to boil (sterilize) bottles, nipples, and rings before use.

Use

Wash your hands, surfaces, and utensils
Pour water into clean bottle (see mixing guide)

Add 1 unpacked level scoop (8.6 g) to each 2 fl oz of water
Return dry scoop to holder in lid

Cap bottle; shake well; attach nipple
Once feeding begins, use within 1 hour or discard

Storage

Once mixed, store bottles in refrigerator and **feed to baby within 24 hours.** Store unopened or opened container at room temperature; avoid extreme temperatures. **Use opened container contents within 1 month.** Do not reuse container.

Warning

Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor. **Never use a microwave to warm formula.** Serious burns can result.

MIXING GUIDE

Measure water	+	Add scoop(s) of unpacked level powder using enclosed scoop
2 fl oz		1 scoop (8.6 g)
4 fl oz		2 scoops
6 fl oz		3 scoops
8 fl oz		4 scoops

Each scoop adds about 0.2 fl oz to the amount of prepared formula.

For larger size mixing instructions, please visit **www.Similac.com/mixinginfo**

When mixed as directed, makes approx. 293 fl oz of formula.

Our **Feeding Expert hotline** is available to help you with feeding questions: **800-986-8800**

Scan to Save!

0 70074 68068 2

Breast milk is recommended. If you choose to use infant formula, the makers of Similac have a formula that's right for your baby.

Have product-related questions?
Call 1-800-515-7677, se habla español 8:30 am – 5:00 pm, Eastern time, weekdays. **www.Similac.com**

DO NOT USE IF OUTER QUALITY SEAL OR INNER FOIL SEAL IS DAMAGED.

Pat. www.abbott.us/patents

15 15

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	09-Jan-2023	CTU Received Date	09-Jan-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)		

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☑ Noticed a problem with the quality of the product ☑ Had problems after switching from one product maker to another maker
	Date the problem occurred	08-Jan-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I recently started to give my baby the Similac 360 Total Care 8oz ready-to-use formula besides my Enfamil ones, but I noticed multiple times of her dark green watery stools which look like diarrhea very much, and I could hear the diarrhea-like sound in her belly shortly after consuming the formula. I never found this problem after using the Enfamil Nueropro ready-to-use formula in any size. And since the use of the Similac ones, my baby seems to have become tempered, she won't eat quietly as she used to be, no matter bottles or breast milk. I suspect that there are quality issue with these 8oz packagings.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

	Department		
	Reporter Speciality		
	Today's date	22-Apr-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

MEDSUN MANDATORY AND VOLUNTARY REPORT FORM

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018 See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #	
UF/Importer Report #	4500150000-2023-8001
	FDA Use Only

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

1. **Patient Identifier**	2. **Age**	3. **Sex**	4. **Weight**
--CONFIDENTIAL--	☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)	☐ Female ☐ Male	☐ lb ☐ kg
In Confidence	or Date of Birth *(e.g., 08 Feb 1925)* __ – ___ – ____		

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/La ino
☐ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☐ **Product Problem** *(e g., defects/malfunctions)*

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* __ – ___ – ____
☐ Life-threatening
☐ Disability or Permanent Damage
☐ Hospitalization – initial or prolonged
☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)*	4. **Date of this Report** *(dd-mmm-yyyy)*
10 – Feb – 2023	__ – Feb – 2023

5. **Describe Event or Problem**
[Event description information is on page 3, Section B.5.]

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc)*
Preexisting characteristics that may have contributed to the event:

C. SUSPECT PRODUCT(S)

1. **Name, Manufacturer/Compounder, Strength**

#1 – Name and Strength	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

2. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. **Dose**	**Frequency**	**Route Used**
#1		
#2		

4. **Therapy Dates** *(If unknown, give duration)* from/to *(or best estimate))* *(dd-mmm-yyyy)*
#1
#2

5. **Diagnosis for Use** *(Indication)*
#1
#2

6. **Is the Product Compounded?**	7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No	#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 __ – ___ – ____ #2 __ – ___ – ____

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**
Similac NeoSure 22 RTF

2. **Common Device Name**	2b. **Procode**
Infant Formula	

3. **Manufacturer Name, City and State**
Abbott Nutrition

4. **Model #**	**Lot #** 41792X8	5. **Operator of Device**
Catalog #	**Expiration Date** *(dd-mmm-yyyy)* __ – Jun – 2023	☐ Health Professional ☐ Lay User/Patient ☐ Other
Serial #	**Unique Identifier (UDI) #**	

6. **If Implanted, Give Date** *(dd-mmm-yyyy)*	7. **If Explanted, Give Date** *(dd-mmm-yyyy)*
– –	– –

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☒ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☒ No ☐ Returned to Manufacturer on: __ – ___ – ____

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

E. INITIAL REPORTER

1. **Name and Address**

Last Name: (b) (6)	First Name: (b) (6)
Address: (b) (6)	
City: (b) (6)	State/Province/Region: TX
Country: USA	ZIP/Postal Code: (b) (6)
Phone #: (b) (6)	Email: (b) (6)

2. **Health Professional?**	3. **Occupation** *(Select from list)*	4. **Initial Reporter Also Sent Report to FDA**
☒ Yes ☐ No	Risk Manager	☐ Yes ☐ No ☐ Unk

MEDWATCH

FORM FDA 3500A (10/15) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One**
☒ User Facility ☐ Importer

2. **UF/Importer Report Number**
4500150000-2023-8001

3. **User Facility or Importer Name/Address**
(b) (6)

4. **Contact Person**
(b) (6)

5. **Phone Number**
(b) (6)

6. **Date User Facility or Importer Became Aware of Event** *(dd-mmm-yyyy)*
__ - ___ - ____

7. **Type of Report**
☒ Initial
☐ Follow-up # _____

8. **Date of This Report** *(dd-mmm-yyyy)*
__ - Feb - 2023

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____

11. **Report Sent to FDA?** *(If Yes, enter date (dd-mmm-yyyy))*
☐ Yes __ - ___ - ____
☐ No

12. **Location Where Event Occurred**
☒ Hospital
☐ Home
☐ Nursing Home
☐ Outpa ient Treatment Facility
☐ Outpa ient Diagnostic Facility
☐ Ambulatory Surgical Facility
☒ Other: NICU *(Specify)*

13. **Report Sent to Manufacturer?** *(If Yes, enter date (dd-mmm-yyyy))*
☐ Yes __ - ___ - ____
☐ No

14. **Manufacturer Name/Address**
Abbott Nutrition

G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
Name
Address
Email Address
Compounding Outsourcing Facility 503B? ☐ Yes

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representa ive
☐ Distributor
☐ Other:

4. **Date Received by Manufacturer** *(dd-mmm-yyyy)*
__ - ___ - ____

5.
NDA # _____
ANDA # _____
IND # _____
BLA # _____
PMA/ 510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction

2. **If Follow-up, What Type?**
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evalua ion

3. **Device Evaluated by Manufacturer?**
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. **Device Manufacture Date** *(dd-mmm-yyyy)*
__ - ___ - ____

5. **Labeled for Single Use?**
☐ Yes ☐ No

6. **Event Problem and Evaluation Codes** *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____
Method _____ - _____ - _____ - _____
Results _____ - _____ - _____ - _____
Conclusions _____ - _____ - _____ - _____

7. **If Remedial Action Initiated, Check Type**
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notifica ion
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: _____

8. **Usage of Device**
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

B.5. **Describe Event or Problem** *(continued)*

Event title: --CONFIDENTIAL--

Describe the event or problem: At approximately 2330, a staff member from our NICU (neonatal intensive care unit) retrieved an unexpired infant formula to feed an infant patient. The formula appeared to be spoiled and unsafe to use. The Staff member noticed that formula Sim Neo sure 22 RTF, Lot #41792X8, expiring on 06/01/23, was sour smelling and clumpy even after shaking. The Unit Tech did not feed the formula to the baby but threw it away.

What was the original intended procedure? : Infant feeding.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.2 and/or D.11; please distinguish)*

Other Remarks

Other Remarks *(For continuation of A and/or D; please distinguish)*

Additional Information for Device #1 :
==========
Is this a laboratory device or laboratory test? [No]
==========

Additional Information for Patient #1 :
==========
Other information about the patient that may have influenced the outcome of the event: Formula did not reach infant.
==========

UF/Importer Report # 4500150000-2023-8001

Other Remarks *(For continuation of B5)*

MEDSUN MANDATORY AND VOLUNTARY REPORT FORM

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018 See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #

UF/Importer Report # 0533050000-2023-8014

FDA Use Only

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

1. **Patient Identifier** --CONFIDENTIAL-- In Confidence

2. **Age** 1 ☒ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)
or Date of Birth *(e.g., 08 Feb 1925)* __ – ___ – ____

3. **Sex** ☒ Female ☐ Male

4. **Weight** ☐ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/La ino
☐ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☒ **Product Problem** *(e g., defects/malfunctions)*

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* __ – ___ – ____
☐ Life-threatening
☐ Disability or Permanent Damage
☐ Hospitalization – initial or prolonged
☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)* 06 – Aug – 2023

4. **Date of this Report** *(dd-mmm-yyyy)* __ – Aug – 2023

5. **Describe Event or Problem**
[Event description information is on page 5, Section Other Remarks]

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc)*

C. SUSPECT PRODUCT(S)

1. **Name, Manufacturer/Compounder, Strength**

#1 – Name and Strength	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

2. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. Dose	Frequency	Route Used
#1		
#2		

4. **Therapy Dates** *(If unknown, give duration)* from/to *(or best estimate))* *(dd-mmm-yyyy)*
#1
#2

5. **Diagnosis for Use** *(Indication)*
#1
#2

6. **Is the Product Compounded?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 __ – ___ – ____ #2 __ – ___ – ____

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name** Abbott Nutrition

2. **Common Device Name** Abbott bottles
2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** 00875
Catalog #
Serial #

Lot # 54031VY00, 53026VY00
Expiration Date *(dd-mmm-yyyy)* __ – ___ – ____
Unique Identifier (UDI) #

5. **Operator of Device**
☐ Health Professional
☐ Lay User/Patient
☐ Other

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* – –

7. **If Explanted, Give Date** *(dd-mmm-yyyy)* – –

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)*
☒ Yes ☐ No ☐ Returned to Manufacturer on: __ – ___ – ____

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

E. INITIAL REPORTER

1. **Name and Address**

Last Name: (b) (6) First Name: (b) (6)
Address: (b) (6)
City: (b) (6) State/Province/Region: CA
Country: USA ZIP/Postal Code: (b) (6)
Phone #: (b) (6) Email: (b) (6)

2. **Health Professional?** ☒ Yes ☐ No

3. **Occupation** *(Select from list)* Other

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk

MEDWATCH

FORM FDA 3500A (10/15) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One**
☒ User Facility ☐ Importer

2. **UF/Importer Report Number**
0533050000-2023-8014

3. **User Facility or Importer Name/Address**
(b) (6)

4. **Contact Person**
(b) (6)

5. **Phone Number**
(b) (6)

6. **Date User Facility or Importer Became Aware of Event** *(dd-mmm-yyyy)*
__ - ___ - _____

7. **Type of Report**
☒ Initial
☐ Follow-up # _____

8. **Date of This Report** *(dd-mmm-yyyy)*
__ - Aug - 2023

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____

11. **Report Sent to FDA?** *(If Yes, enter date (dd-mmm-yyyy))*
☐ Yes __ - ___ - _____
☐ No

12. **Location Where Event Occurred**
☒ Hospital
☐ Home
☐ Nursing Home
☐ Outpa ient Treatment Facility
☐ Outpa ient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. **Report Sent to Manufacturer?** *(If Yes, enter date (dd-mmm-yyyy))*
☐ Yes __ - ___ - _____
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
Name
Address
Email Address
Compounding Outsourcing Facility 503B? ☐ Yes

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representa ive
☐ Distributor
☐ Other:

4. **Date Received by Manufacturer** *(dd-mmm-yyyy)*
__ - ___ - _____

5.
NDA # _____
ANDA # _____
IND # _____
BLA # _____
PMA/ 510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction

2. **If Follow-up, What Type?**
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evalua ion

3. **Device Evaluated by Manufacturer?**
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. **Device Manufacture Date** *(dd-mmm-yyyy)*
__ - ___ - _____

5. **Labeled for Single Use?**
☐ Yes ☐ No

6. **Event Problem and Evaluation Codes** *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____
Method _____ - _____ - _____ - _____
Results _____ - _____ - _____ - _____
Conclusions _____ - _____ - _____ - _____

7. **If Remedial Action Initiated, Check Type**
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notifica ion
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: _____

8. **Usage of Device**
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

UF/Importer Report # 0533050000-2023-8014

B.5. **Describe Event or Problem** *(continued)*

[Event description information is on page 5, Section Other Remarks]

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.2 and/or D.11; please distinguish)*

Other Remarks

Other Remarks *(For continuation of A and/or D; please distinguish)*

Other Remarks *(For continuation of B5)*

Event title: --CONFIDENTIAL--

Describe the event or problem: Situation:
Mother of patient (MOP) reached out to provider (MD) and registered dietitian (RD) via MyChart message to inform them that they had been using the "Abbott plastic bottles provided by the hospital" to measure water for patient's formula. Family recently purchased different brand name bottles and when they poured the 6.5 ounces of water, as measured in the Abbott bottle, into the new bottles (Dr Brown and Everflow), it measured to the 7 ounce line in both bottles. In a later message, MOP confirmed that she also poured the 6.5 ounces of water, as measured in the Abbott bottles, into a household measuring cup and it also measured at 7 ounces. MOP expressed concern that if the volume of water she has been using in the formula recipe is more than the volume recommended, the caloric concentration of the formula may have been less than intended, which may have contributed to her daughter's history suboptimal weight gain.
Background:
Patient is an 18 month old (15 month corrected) ex-25 weeker with dysphagia, GERD, tracheobronchomalacia, FTT, and subglottic cysts who is GT dependent. She was last seen in GI clinic on 6/21/23 at which time she was transitioned from an infant to pediatric formula and given updated mixing instructions for the new formula (Neocate Jr -- Mix 4 scoops 5 oz water = ~25 kcal/oz). Patient has a GT and MOP has been using the Abbott bottle to measure the water she mixes with the patient's formula before mixing and providing to the patient.
Assessment:
The possible inaccuracy of the Abbott bottles was brought to the attention of (b) (6) management and additional testing using gram weight scales to measure water (1 gram water = 1 mL of water) were performed to assess the accuracy of the marked measurements on the bottle. (b) (6) Manager found discrepancies of measurements at the 120 mL, 150 mL, 180 mL, 200 mL, 210 mL, 250 mL, and 6.5 fluid ounce marks. The (b) (6) Manager of (b) (6), found findings consistent with ours at the 50 mL, 100 mL, 120 mL, 150 mL, and 200 mL marks using various Abbott bottle samples. Testing was completed with various 8 ounce Abbott bottles and discrepancies were found across all bottles (variations from bottle to bottle ranging from 2-11 mL). In one of our tests, each line on the Abbott bottle was below the actual amount of water required to equal the designated volume of water. For example, when to the 6.5 fluid ounce line (consistent with ~192 mL of water or ~192 grams of water), the actual amount measured to reach the marked line was ~188 mL or ~188 grams of water. When we filled water up to the 6.5 fluid ounce line, it was actually less water than it should have been. This is the same way of saying in order to reach a certain weight of water (e.g 200 grams) it required us filling the bottle up to ~210 mL (above the marked line) to achieve the correct measurement.
Recommendation:
Given the large discrepancy found between different bottle samples using the same 8 ounce Abbott bottle product, we are recommending for 8 ounce bottles to be removed from the food service department and hospital units and no longer be used in patient care, or be handed out to patients and their families upon discharge. In an effort to provide education to families, we are also proposing the development of an educational handout that could list example products (gram weight scales and volume measurements) that could be provided to families during discharge education to ensure that families are aware of how to accurately measure water when mixing formula.

8/22: lot numbers of boxes in which bottles were tested were 54031VY00, 53026VY00, and 53027VY00. (b) (6) has removed these from circulation and have in-serviced staff not to use these bottles. I have given all bottles left on hand in Food Services to Abbott Nutrition rep Michelle Anderson
((b) (6) Manager) has coordinated with Michelle Anderson (Abbott Representative) to have a couple cases of these 8 oz plastic milk bottles (item 1040/REF 00875) picked up so Abbott's Quality Assurance team can review the volumetric discrepancies found

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What problem did the user have (Check all that apply) :Other;