FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-1802 | Department: CFSAN | RCT No.: RCT-1089940 | CTU Triage Date: 09-Jan-2023 | Total Page s: 6

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

Company UnitCDER-CTUOriginating AccountFAERSSource MediumMWO (Drug)Source Form TypeE2B XML 3500BPriorityRoutineOverride Auto Calculation RuleNoFDA Received Date09-Jan-2023CTU Received Date09-Jan-2023CTU Triage DateImage: CTU Data Entry DateImage: CTU Data Entry DateImage: CTU Data Entry Date	Basic Details	asic Details						
Priority Routine Override Auto Calculation Rule No FDA Received Date 09-Jan-2023 CTU Received Date 09-Jan-2023	Company Unit	CDER-CTU	Originating Account	FAERS				
Override Auto Calculation Rule No FDA Received Date 09-Jan-2023 CTU Received Date 09-Jan-2023	Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B				
FDA Received Date 09-Jan-2023 CTU Received Date 09-Jan-2023	Priority	Routine						
	Override Auto Calculation Rule	No						
CTU Triage Date CTU Data Entry Date	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	Report Type	Spontaneous	Report Classification	Drug				
Assign To User	Assign To	User		,				
User/Group	User/Group							
Forward to Department	Forward to Department							
Case Priority Direct	Case Priority	Direct						

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

Se	ection 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.

R	Relevant Test/Laboratory Data 1 of 1					
	Test Name		Test Date			
	Test Result		Test Unit			
	Low Test Range		High Test Range			
	More Information Available?					

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-1802 | Department: CFSAN | RCT No.: RCT-1089940 | CTU Triage Date: 09-Jan-2023 | Total Page

s: 6

Additional Comments				
Section B - Product Availability				
				<u> </u>
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			
Туре	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	Similac 360 Total Care Infan	t Formula, with 5 HMO Prebioti	CS	
names as you see)				
Name of the company that makes (or compounds) the product	Abbott			
Product Type(check all that apply)	Over-the-Counter			
Strength		If Other		
NDC number	L			
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				

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-1802 | Department: CFSAN | RCT No.: RCT-1089940 | CTU Triage Date: 09-Jan-2023 | Total Page s: 6

Give best estimate of duration	2 Month	
Is therapy still on-going?		
Why was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
Returned to Manufacturer On		
Section D - About the Medical De	evice	
Name of medical device		
Name of the company that makes the medical device Other identifying information (The locate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
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 O	NLY (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 Wh	o 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 Ative Hawaiian or Other Pacific Islander Asian White Black or African American	

CTU No.: FDA-CDER-CTU-2023-1802 | Department: CFSAN | RCT No.: RCT-1089940 | CTU Triage Date: 09-Jan-2023 | Total Page s: 6

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.

ection F - About the Perso	h 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		

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-1802 | Department: CFSAN | RCT No.: RCT-1089940 | CTU Triage Date: 09-Jan-2023 | Total Page s: 6

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	



FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-10715 | Department: CFSAN | RCT No.: RCT-1101745 | CTU Triage Date: 07-Feb-2023 | Total Pag es: 7

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

asic 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				

Co	Contact						
-	ase eporter	First Name		Last Name	Email Address	Phone	
(b) (6)			(b) (6)				
Se	ection 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 lon Required help to prevent permanent ha Disability or health problem Birth defect Life-threatening Death Dther serious/important medical incider	rm			
4.	Fell us wł	hat happened and how	v it h	appened (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					
	Test Name		Test Date		
	Test Result		Test Unit		
	Low Test Range		High Test Range		
	More Information Available?				

	Iditional Comments				
					-
Se	ection 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			
ISe	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
-	Туре	Drug/Biologic			
	This report is about	Food/Medical food			
-	Name of the product as it	Similac Soy Isomil			
	appears on the box, bottle, or package (Include as many names as you see)				
	Name of the company that makes (or compounds) the product	Abbott			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic			
		Biosimilar			
	Strength	If Other			
	NDC number]	1
	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			
Dr	ug 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				

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-10715 | Department: CFSAN | RCT No.: RCT-1101745 | CTU Triage Date: 07-Feb-2023 | Total Pag es: 7

	Give best estimate of duration			
	Is therapy still on-going?			
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat) 1 of 1	
	Infant formula as supplemental nu			
	Returned to Manufacturer On			
Se	ction D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem occurred?			
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast implants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o 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 Nati Native Hawaiian or Other Pacif Asian White Black or African American		

CTU No.: FDA-CDER-CTU-2023-10715 | Department: CFSAN | RCT No.: RCT-1101745 | CTU Triage Date: 07-Feb-2023 | Total Pag

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

es: 7

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

tion F - About the Person	n 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	

CTU No.: FDA-CDER-CTU-2023-10715 | Department: CFSAN | RCT No.: RCT-1101745 | CTU Triage Date: 07-Feb-2023 | Total Pag es: 7

45445RE 250 USE/BY 1APR2024 1902 ISOPWD

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

> 43629RE 190 USE/BY 1FEB2024 1429 ISOPWD



FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-15910 | Department: CFSAN | RCT No.: RCT-1108488 | CTU Triage Date: 27-Feb-2023 | Total Pag es: 7

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)			

Sectio	Section A - About the Problem				
	hat kind of problem was it? heck 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			
Da	ate the problem occurred	22-Feb-2023			
Se	erious	No			
	d any of the following happen? heck 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	Τε	est Date	
Test Result	Τε	est Unit	
Low Test Range	Hi	ligh Test Range	
More Information Available?			

Additional Comments				
Section B - Product Availability	1		-	
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	I			1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it	Similac sensitive			
appears on the box, bottle, or package (Include as many names as you see)				
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			
Strength	Biosimilar	If Other		
NDC number		ii otiloi		
Did the problem stop after the	Yes			
person reduced the dose or stopped taking or using the product?				
Did the problem return if the	Yes			
person started taking or using the product again?				
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				

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-15910 | Department: CFSAN | RCT No.: RCT-1108488 | CTU Triage Date: 27-Feb-2023 | Total Pag es: 7

	Give best estimate of duration				
	Is therapy still on-going?				-
Wł	ny was the person using the pr	oduct? (such as what cor	dition was it supposed to tre	eat) 1 of 1	
	11 month old infant				
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Otl loc	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the ex	xpiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem occurred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out relevant)	(If	
Se	ction E - About the Person Wr	no 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 Nati Native Hawaiian or Other Pacifi 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.

None

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

None

Section F - About the Person	n 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		

Similac SENSITIVE

NO PALM OLEIN OIL

NO ARTIFICAL

GROWTH &

DEVELOPMENT

0-D

VITAMIN E

For Fussiness & Gas Due to Lactose Sensitivity

BRAIN NOURISHING DHA

Abbott

EYE HEALTH LUTEIN

OptiGRO

INT FORMULA WITH IRON



FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-24539 | Department: CFSAN | RCT No.: RCT-1119153 | CTU Triage Date: 31-Mar-2023 | Total Pag es: 5

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

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-24539 | Department: CFSAN | RCT No.: RCT-1119153 | CTU Triage Date: 31-Mar-2023 | Total Pag es: 5

	Low Test Range	0	High Test Range	20			
	More Information Available?						
Ad	dditional Comments						
Se	ction 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					
Se	ction C - About the Products			1 of 1			
	Suspect	Yes			\square		
	Primary?	Yes					
	Туре	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 of Generic Biosimilar	or an Outsourcing Facility				
	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					
Dru	ug Therapy			1 of 1			
	Expiration date	01-Dec-2024					
	Lot number						
	Dosage Form	011	- K OH	2			
	Quantity	Other		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					

Receipt No: RCT-1119153 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-24539 | Department: CFSAN | RCT No.: RCT-1119153 | CTU Triage Date: 31-Mar-2023 | Total Pag es: 5

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 pr	oduct? (such as what co	ndition was it supposed to treat)	1 of 1
Baby formula			
Returned to Manufacturer On			
Section D - About the Medical De	avico		
Name of medical device			
Name of the company that			
makes the medical device			
Other identifying information (The locate them)	e model, catalog, lot, seri	al, or UDI number, and the expira	tion date, if you can
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 O	NLY (such as pacemake	ers, breast implants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Person Wh	o 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

Ethnicity (Choose only one)

Race (Check all that apply)

Weight

12.6 kg

Not Hispanic/Latino

American Indian or Alaska Native

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-24539 | Department: CFSAN | RCT No.: RCT-1119153 | CTU Triage Date: 31-Mar-2023 | Total Pag es: 5

\square	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 Perso	n 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)	

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-24539 | Department: CFSAN | RCT No.: RCT-1119153 | CTU Triage Date: 31-Mar-2023 | Total Pag es: 5

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		

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-30162 | Department: CFSAN | RCT No.: RCT-1125032 | CTU Triage Date: 24-Apr-2023 | Total Pag es: 8

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	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	ection 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)	product? (check yes if you are			
Section C - About the Products			1	of 1
Suspect	Yes			
Primary?	Yes			
Туре	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	bbott		
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	Compounded by a Pharmacy or an Outsourcing Facility Generic		
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				

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-30162 | Department: CFSAN | RCT No.: RCT-1125032 | CTU Triage Date: 24-Apr-2023 | Total Pag es: 8

	Give best estimate of duration	6 Hour	
	Is therapy still on-going?	Yes	
Wł	y was the person using the pr	oduct? (such as what condition was it supposed to treat)	1 of 1
	Nutritional Formula for infants with	n GI upset	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
Oti loc	Name of the company that makes the medical device ner identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if yc	ou can
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ite the implant was put in	Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wr	no 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 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

tion F - About the Perso		1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
_ast name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	ТХ	
Country	UNITED STATES	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		

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	





CTU No.: FDA-CDER-CTU-2023-30162 | Department: CFSAN | RCT No.: RCT-1125032 | CTU Triage Date: 24-Apr-2023 | Total Pa es: 8

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-57020 | Department: CFSAN | RCT No.: RCT-1152268 | CTU Triage Date: 07-Aug-2023 | Total Pag es: 7

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			

Co	ontact						
-	ase eporter	First Name	Last Name	Er	mail Address	Phone	
	2	(b) (6)					
Se	ection A -	About the Problem					
		nd of problem was it? all that apply)	Used a product incorrectly w Noticed a problem with the o	which could have			
	Date the	problem occurred	02-Aug-2023				
	Serious		No				
		of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death Other serious/important med	rmanent harm	ease 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).

R	elevant 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		
Туре	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 of Generic Biosimilar	or an Outsourcing Facility	
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	king 02-Aug-2023		
Date the person reduced dose of the product	se of		

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-57020 | Department: CFSAN | RCT No.: RCT-1152268 | CTU Triage Date: 07-Aug-2023 | Total Pag es: 7

	Give best estimate of duration			
	Is therapy still on-going?	Yes		
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat) 1 of 1	
	Breast milk supplement			
	Returned to Manufacturer On			
Se	ction D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot loc	ner identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem occurred?			
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast implants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o 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 Nati Native Hawaiian or Other Pacif Asian White Black or African American		

CTU No.: FDA-CDER-CTU-2023-57020 | Department: CFSAN | RCT No.: RCT-1152268 | CTU Triage Date: 07-Aug-2023 | Total Pag es: 7

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 Fil	ing Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(h) (c)	
Middle Name	(b) (6)	
First name		
Number/Street		
City		
State/Province	NY	
Country	UNITED STATES	
ZIP or Postal code	(h) (c)	_
Telephone number	(b) (6)	-
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

CTU No.: FDA-CDER-CTU-2023-57020 | Department: CFSAN | RCT No.: RCT-1152268 | CTU Triage Date: 07-Aug-2023 | Total Pag es: 7

49167630 USE/BY 1FEB2025

49167630 USE/BY 1FEB2025 1345 016 ELECARE

1345 016 ELECARE



FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-59113 | Department: CFSAN | RCT No.: RCT-1154406 | CTU Triage Date: 15-Aug-2023 | Total Pag es: 7

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				

Co	Contact						
1	ase eporter				Email Address		Phone
Ŀ	(b) (6)		(b) (6)		(b) (6)		(b) (6)
Se	ection 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)		Required help to Disability or hea Birth defect Life-threatening Death Other serious/in	portant medical incide	rm nt(Please Describe Below)		
		nat happened and how nal documents if nece		Include as many	/ details as possible F	DA may	reach out to you for
	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.

R	elevant 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?			

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-59113 | Department: CFSAN | RCT No.: RCT-1154406 | CTU Triage Date: 15-Aug-2023 | Total Pag es: 7

Re	elevant Test/Laboratory Data			2 of 2	
	Test Name	CSF CULTURE WHITE C	Test Date	11-Aug-2023	
	Test Result	13	Test Unit	MICROGRAMS PER LITR E	
	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

Section C - About the Products	s 1 of 1	
Suspect	Yes	
Primary?	Yes	
Туре	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 t product again?		
Drug Therapy	1 of 1	
Expiration date	01-May-2025	
Lot number	52593H40	
Dosage Form		

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-59113 | Department: CFSAN | RCT No.: RCT-1154406 | CTU Triage Date: 15-Aug-2023 | Total Pag es: 7

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 C Date the implant was put in		akers, breast implants, etc.)	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?			
Catalog Number Lot Number Serial Number UDDI Number Expiration date			
Catalog Number Lot Number Serial Number UDDI Number			
Catalog Number Lot Number Serial Number			
Catalog Number			
Model Number			
Other identifying information (The locate them)	e model, catalog, lot, s	erial, or UDI number, and the	e expiration date, if you can
makes the medical device			
Name of the company that			
Name of medical device			
Section D - About the Medical De			
Returned to Manufacturer On			
Why was the person using the p Baby formula		condition was it supposed to	
Is therapy still on-going?	aduat2 (auch as what	condition was it awaraad to	treat) 1 of 1
Give best estimate of duration			
Date the person reduced dose of the product			
Date the person stopped taking or using the product	10-Aug-2023		
Date the person first started taking or using the product	26-Jul-2023	L	
		If Other	
How was it taken or used		If Other	
Frequency How was it taken or used			

Se	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)					

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-59113 | Department: CFSAN | RCT No.: RCT-1154406 | CTU Triage Date: 15-Aug-2023 | Total Pag

es: 7

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

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-59113 | Department: CFSAN | RCT No.: RCT-1154406 | CTU Triage Date: 15-Aug-2023 | Total Pag es: 7

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

CTU No.: FDA-CDER-CTU-2023-59113 | Department: CFSAN | RCT No.: RCT-1154406 | CTU Triage Date: 15-Aug-2023 | Total Pag es: 7 i..... ů. 00 15 hund (() (1) 23 Helt. 5H26. 10 000 à

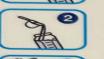
USE BY DATE ON CONTAINER . USE AS DIRECTED BY A DOCTOR **Directions for Preparation and Use**

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.





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

Once mixed, store bottles in refrigerator and feed to baby within Storage 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.

	MIX	ING GUIDE
Measure water	+	Add scoop(s) of unpacked level powder using enclosed scoop
6 fl oz 8 fl oz		1 scoop (8.6 g) 2 scoops 3 scoops 4 scoops
Each scoop ad	ds about 0.2	fi oz to the amount of prepared
For larger size	e mixing ins	tructions, please visit
Manual Cincilas	com/mixin	akes approx. 293 fl oz of formula.

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



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Breast milk is recommended. If you choose to use infant formula, the makers of Similac have a formula that's right for your baby. Call 1800-515-7677, 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



FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-1802 | Department: CFSAN | RCT No.: RCT-1089940 | CTU Triage Date: 09-Jan-2023 | Total Page s: 6

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

Company UnitCDER-CTUOriginating AccountFAERSSource MediumMWO (Drug)Source Form TypeE2B XML 3500BPriorityRoutineOverride Auto Calculation RuleNoFDA Received Date09-Jan-2023CTU Received Date09-Jan-2023CTU Triage DateImage: CTU Data Entry DateImage: CTU Data Entry DateImage: CTU Data Entry Date	Basic Details								
Priority Routine Override Auto Calculation Rule No FDA Received Date 09-Jan-2023 CTU Received Date 09-Jan-2023	Company Unit	CDER-CTU	Originating Account	FAERS					
Override Auto Calculation Rule No FDA Received Date 09-Jan-2023 CTU Received Date 09-Jan-2023	Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B					
FDA Received Date 09-Jan-2023 CTU Received Date 09-Jan-2023	Priority	Routine							
	Override Auto Calculation Rule	No							
CTU Triage Date CTU Data Entry Date	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	Report Type	Spontaneous	Report Classification	Drug					
Assign To User	Assign To	User		,					
User/Group	User/Group								
Forward to Department	Forward to Department								
Case Priority Direct	Case Priority	Direct							

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

Se	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.

R	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	

U.S. Department of Hea				ATORY AND			REPORT		Form Appr	oved: OM	1B No. 0910)-0291, Ex PRA s	xpires: 9/30/2018 Setatement on revers
Food and Drug Administration importers, distributors				and manufacturers									
MEDWATC			for M.	ANDATOR	-	orting		UF/I	mporter Re	eport #	450015	0000-2	2023-8001
FORM FDA 3500A	4 (10/15)			Page 1 o	5 10								FDA Use On
Note: For date prompts abbreviation, and 4-dig			igit day, 3-letter	month	3. #1	Dose			Frequenc	у	Route U	sed	
	n jour, ior champ	.,											
1. Patient Identifier	2. Age Year	(s) Month(s	3. Sex	4. Weight	#2	-		_		_			
CONFIDENTIAL	Wee		6										
	or Date of Birth (e.		Female		4. T	nerapy Date	es (If unkn	own, aiv	e duration) from/	9. Ever	nt Abate	d After Use
In Confidence			Male		to	(or best es							Dose Reduced?
5.a. Ethnicity (Check	5 h Race (C)	eck all that apply	1		#1						#1 🗌	Yes	No Doesn'
single best answer)	17 DI 18	American India		ative	#2								apply
Hispanic/La ino	Black or A	African American	White		5. DI #1	iagnosis fo	or Use (Ind	lication)			#2	Yes	No Doesn'i apply
Not Hispanic/Latino	Native Ha	waiian or Other P	acific Islander								10 54	nt Dean	
B. ADVERSE EV	ENT OR PRO	DUCT PROB	LEM		#2							ntroduct	peared After tion?
1. Adverse Event	and/or	Product Problem	n (e g., defects/n	nalfunctions)				5			#1	Yes 🗌	No Doesn'
2. Outcome Attributed	to Adverse Ever	nt (Check all that	apply)			the Production			e Product Counter?	t Over-			apply
Death Include da	te (dd-mmm-yyyy)	×	<u></u>		#1	Ves		#1 [No	#2	Yes	
Life-threatening		Disability	or Permanent I	Damage	#2			#2 [apply
Hospitalization – in			al Anomaly/Birt	h Defects	0.000	Yes	No			No			
Other Serious (Imp			10		8. E) #1	xpiration D	ate (dd-mi	тт-уууу	/) #2				
Required Interventi	CPO E SUM DU SI SI MULTUN DU SU DU SU		1011001010000										
3. Date of Event (dd-m 1 0 - Feb -		4. Date of this I	10 No.			SUSPEC		GALL	DEVICE	1			
5. Describe Event or F		1	<u>eb_202</u>			ilac Ne		2 RTF					
[Event descrip B.5.]		ation is on	page 3, S	ection		ommon De ant Form		e					2b. Procode
of sectors (Fig. , as Plant					3. Manufacturer Name, City and State Abbott Nutrition								
					4 M	odel #			ot#			5 On	erator of Device
6. Relevant Tests/Lab	oratory Data Inc	luding Dates						41792X8 🗌 Health					
		9				Catalog # Expiration Date (dd: 							
					S	Serial # Unique Identifier (UDI) #					ther		
					6 If	Implanted,	Give Date	e (dd-mn		7 If Fx	planted (Give Dat	e (dd-mmm-yyyy)
7. Other Relevant Hist	tony Including Dr	acting Madia	Conditions	0.0		100 G <u>e</u> l	5 <u>72</u>	8			-	-	(dd-1111111-yyyy)
allergies, pregnancy,						this a sing processed					Yes		D
Preexisting c to the event:		.cs that may	have cont	ributed	9. lf	Yes to Iten	n 8, Enter	Name a	nd Addres	ss of Re	process	or	
	ODUCT(S)					Device Ava							
C. SUSPECT PR		strength				Yes 🛛	No	Returne	ed to Manu	ifacturer	on:		
#1 – Name and Strengt			#1 - NDC # or	Unique ID	11. 0	Concomita	nt Medica	I Produ	cts and Th	erapy D	Dates (Ex	clude trea	atment of event)
#1 - Manufacturer/Com	npounder		#1 – Lot #		1								
#2 – Name and Strengt	th		#2 - NDC # or	Unique ID		INITIAL I	REPOR	TER					
#2 - Manufacturer/Com	npounder		#2 – Lot #		100000	ame and A							
	13					Name: (b)				First N	ame:(b)	(6)	
2. Concomitant Medic	2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)					ress: (b) (6					(~)		
						(b) (6)			Sta	te/Provir	nce/Regio	n: TX	
					0.00	ntry: USA				-	ostal Cod		i)
					Phor	ne #: (b) (6	<u>5)</u>		Email:	(b) (6)			
Submission of a rep	ort does not c	onstitute an ad	mission that	medical	2. He	and the second	3.0)ccupati	on (Select t			Initial Re Report to	eporter Also Sen
personnel, user faci	ility, importer, o	distributor, ma				Yes		sk Manage	er			10	No Unk
caused or contribut	ed to the event	23										_ 103	

MEDWATCH

FDA USE ONLY

FORM FDA 3500A	A (10/15) (con	tinued)	Page 2	of 5		
F. FOR USE BY U	JSER FACILIT	Y/IMPORTER (D	evices Only)	H. DEVICE MANUF	ACTURERS ONLY	2. 2
1. Check One		2. UF/Importer F	eport Number	1. Type of Reportable Eve	ent	2. If Follow-up, What Type?
User Facility	Importer	4500150000	-2023-8001	Death		Correction
3. User Facility or Impo	orter Name/Addres	s		Serious Injury		Additional Information
(b) (6)				Malfunction		Response to FDA Request
						Device Evalua ion
				3. Device Evaluated by M	anufacturer?	4. Device Manufacture Date
				Not Returned to M		(dd-mmm-yyyy)
4. Contact Person		5. Phone N	umber	and the second second second second	tion Summary Attached	
(b) (6)		(b) (6)		No (Attach page to	explain why not) or	5. Labeled for Single Use?
6. Date User Facility or		f Report 8.	Date of This Report	provide code:	9200994 (1299) (1299) (1299) (1299) (1299)	Yes No
Importer Became Aw of Event (dd-mmm-yy			(dd-mmm-yyyy)			-
		w-up #	<u> </u>	6. Event Problem and Eva	luation Codes (Refer to c	oding manual)
9. Approximate		n Codes (Refer to codi		Patient Code	-	
Age of Device	Patient			Device		
	Code	-	-	Code		
	Device		_	Method	_	
11 Deport Contac EDA	Code	C Logation Where To				
11. Report Sent to FDA enter date (dd-mmm-		2. Location Where Events	Outpa ient	Results	-	
	-	Home	Diagnostic Facility	Conclusions		
No		Nursing Home	Ambulatory Surgical Facility			
13. Report Sent to Man Yes, enter date (dd-n	ufacturer? (If	Outpa ient Treatmer		7. If Remedial Action Initia	ated, Check Type 8.	Usage of Device
Yes -				Recall	Notifica ion	Initial Use of Device
□	Þ	Other: NICU NICU	(Specify)	Repair	Inspection	Reuse
14. Manufacturer Name				Replace	Patient Monitoring	If action reported to FDA under
Abbott Nut	rition			Relabeling		21 USC 360i(f), list correction/
				Other:		removal reporting number:
G. ALL MANUFA	CTURERS			10. Additional Manufa	acturer Narrative ar	nd / or 11. Corrected Data
1. Contact Office (and		e for Devices)	2. Phone Number			Construction Construction Construction Construction
Name	5	,				
			3. Report Source			
Address			(Check all that apply)			
			Foreign			
			Study			
Email Address						
Linai Address			Health Professional			
Compounding Outsourc	ing Facility 503B?	Yes	User Facility			
4. Date Received by	5.					
Manufacturer (dd-mn		NDA #	Representa ive			
	0 0 0 0 0 0	NDA #	Distributor			
6. If IND, Give Protocol		IND #	Other:			
		BLA# PMA/				
7. Type of Report (Check all that apply)	51	0(k) #				
(Check all that apply)	V Co	mbination				
7-day Period		Product Yes				
10-day Initial		Pre-1938 Yes				
15-day Follow	v-up #	OTC Yes				
9. Manufacturer Report	t Number 8. Ac	lverse Event Term(s)				
		.,				
				Decederate (11, 11, 11, 11)	Car inter	OND Conterment #4
This section applies	s only to requirem	ents of the Paperwor	k Reduction Act of 1995.	Department of Health and H	uman Services	OMB Statement: "An agency may not

The public reporting burden for his collection of information has been estimated to average 73 minutes per response, including he time for reviewing instructions, searching existing data sources, ga hering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collec ion of information, including suggestions for reducing this burden to:

conduct or sponsor, and a person is not required to respond to, a collection of informa ion unless it displays a curren ly Food and Drug Administration Office of Chief Information Officer Paperwork Reduc ion Act (PRA) Staff PRAStaff@ida.hhs gov valid OMB control numt Please DO NOT RETURN this form to the above PRA Staff email address. valid OMB control number.

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

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

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UF/Importer Report # 4500150000-2023-8001

B.5. Describe Event or Problem (continued)

MEDWATCH

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

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

MedWatch	for MANDATORY reporting Page 4 of 5				
FORM FDA 3500A (10/15) (continued)		UF/Importer Report # 4500150000-2023-8001			
Other Remarks (For continuation of A and/or D; please distinguis Additional Information for Device #1 :	,	tion for Patient #1 :			
Is this a laboratory device or laboratory					

Page 5 of 5

UF/Importer Report # 4500150000-2023-8001

Other Remarks (For continuation of B5)

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

MEDWATCH

U.S. Department of Health and Human Servic		AND VOLUNTARY REPO		ved: OMB No. 0910-0291, Expires: 9/30/2018 Se PRA statement on reverse			
Food and Drug Administration		tors and manufacturers					
MEDWATCH		TORY reporting	UF/Importer Rep	0533050000-2023-8014			
FORM FDA 3500A (10/15)	Pag	e 1 of 5		FDA Use Only			
Note: For date prompts of "dd-mmm-yyyy" plea	se use 2-digit day, 3-letter month	3. Dose	Frequency				
abbreviation, and 4-digit year; for example, 01-	ul-2015.	#1					
	Month(s) 3. Sex 4. Weig	ght #2					
CONFIDENTIAL 1 Week(s)	Days(s) Female						
or Date of Birth (e.g., 08	Male	to (or best estimate)	nknown, give duration)) (dd-mmm-yyyy)	from/ 9. Event Abated After Use Stopped or Dose Reduced?			
In Confidence		¢g #1		#1 Yes No Doesn't			
5.a. Ethnicity (Check 5.b. Race (Check a single best answer)	'I that apply) erican Indian or Alaskan Native	#2		apply			
Hispanic/La ino		5. Diagnosis for Use	(Indication)	#2 Yes No Doesn't			
	or Other Pacific Islander	#1		apply			
B. ADVERSE EVENT OR PRODUC	T PROBLEM	#2	#2 10. Event Reapped Reintroduction				
1. W. S	ct Problem (e g., defects/malfunction			#1 Yes No Doesn't			
2. Outcome Attributed to Adverse Event (Ch		6. Is the Product	7. Is the Product				
Death Include date (dd-mmm-yyyy):		Compounded?	the-Counter?	#2 Yes No Doesn't			
Life-threatening	Disability or Permanent Damage	#1 Yes No		No apply			
Hospitalization – initial or prolonged	Congenital Anomaly/Birth Defect			No			
Other Serious (Important Medical Events)		8. Expiration Date (do	and the second se				
Required Intervention to Prevent Permaner	t Impairment/Damage (Devices)	#1	#2	Teeen			
	te of this Report (dd-mmm-yyyy)	D. SUSPECT ME	DICAL DEVICE				
$\frac{0}{6} = \frac{A}{u} \frac{g}{g} = \frac{2}{2} \frac{0}{2} \frac{2}{3}$ 5. Describe Event or Problem	<u> </u>	1. Brand Name Abbott Nutritic	on				
[Event description information Other Remarks]	n is on page 5, Section	Abbott bottles	2. Common Device Name 2b. Procode Abbott bottles 3. Manufacturer Name, City and State				
		4. Model #	Lot #	5. Operator of Device			
6. Relevant Tests/Laboratory Data, Including	Dates	Catalog #		ate (dd-mmm-yyyy) Lay User/Patient			
		Serial #	Unique Ident				
		6. If Implanted, Give I	Date (dd-mmm-yyyy) 7	. If Explanted, Give Date (dd-mmm-yyyy)			
7. Other Relevant History, Including Preexist		8. Is this a single-use					
allergies, pregnancy, smoking and alcohol us	e, liver/kidney problems, etc)		reprocessed and reused on a patient? Yes No 9. If Yes to Item 8, Enter Name and Address of Reprocessor				
			for Evaluation? (Do no				
C. SUSPECT PRODUCT(S) 1. Name, Manufacturer/Compounder, Streng	th		Returned to Manufa				
#1 – Name and Strength	#1 – NDC # or Unique	ID 11. Concomitant Med	lical Products and The	rapy Dates (Exclude treatment of event)			
#1 – Manufacturer/Compounder	#1 – Lot #						
#2 – Name and Strength	#2 – NDC # or Unique	E. INITIAL REPO	DRTER				
#2 - Manufacturer/Compounder	#2 – Lot #	1. Name and Address					
		Last Name: (b) (6)		First Name:(b) (6)			
2. Concomitant Medical Products and Thera	by Dates (Exclude treatment of eve	Address: (b) (6)					
		City: (b) (6)	State	e/Province/Region: CA			
		Country: USA		ZIP/Postal Code: (b) (6)			
		Phone #: (b) (6)	Email: (b) (6)			
Submission of a report does not consti	ute an admission that medic	al 2. Health Professional?	3. Occupation (Select fro	om list) 4. Initial Reporter Also Sent Report to FDA			
personnel, user facility, importer, distril	outor, manufacturer or produ	ct Xes No	Other				
caused or contributed to the event.							

MEDWATCH

FDA USE ONLY

FORM FDA 3500	A (10/15) (con	tinued)	Page 2	of 5		
F. FOR USE BY U	USER FACILIT	Y/IMPORTER (D	evices Only)	H. DEVICE MANUFA	CTURERS ONLY	
1. Check One		2. UF/Importer I		1. Type of Reportable Event		2. If Follow-up, What Type?
User Facility	Importer	0533050000	-2023-8014	Death		Correction
3. User Facility or Impo	orter Name/Addres	s		Serious Injury		Additional Information
(b) (6)				Malfunction		Response to FDA Request
· / · /						Device Evalua ion
				3. Device Evaluated by Man		 Device Manufacture Date (dd-mmm-yyyy)
				Not Returned to Man		
4. Contact Person		5. Phone N	umber	Yes Evaluatio	n Summary Attached	
(b) (6)		(b) (6)		No (Attach page to e provide code:	explain why not) or	5. Labeled for Single Use?
6. Date User Facility or Importer Became Av		Report 8	. Date of This Report (dd-mmm-yyyy)	provide code.		Yes No
of Event (dd-mmm-y			(33			
	Follow	v-up #	<u>– Aug – 2023</u>	6. Event Problem and Evalu	ation Codes (Refer to co	ding manual)
9. Approximate	10. Event Problem	Codes (Refer to cod	ing manual)	Patient Code		-
Age of Device	Patient			Device		
	Code	-	-	Code		
	Device			Method		
44 Dec 10 11 17	Code					
11. Report Sent to FDA enter date (dd-mmm		2. Location Where Ev	Outpa ient	Results		
Yes		☐ Hospital ☐ Home	Diagnostic Facility		3	
No			Ambulatory	Conclusions		
13. Report Sent to Man	nufacturer? (If	Nursing Home Outpa ient Treatme	Surgical Facility	7. If Remedial Action Initiate	ed, Check Type 8.	Usage of Device
Yes, enter date (dd-	mmm-yyyy))	Facility		Recall	Notifica ion	Initial Use of Device
Yes	[Other:	(0	Repair I	nspection	Reuse
14. Manufacturer Name	o/Addresse		(Specify)	Replace	Patient Monitoring	Unknown
14. Manufacturer Name	erAddress				nounoutons	If action reported to FDA under 21 USC 360i(f), list correction/
						removal reporting number:
				Other:		
2						
G. ALL MANUFA	CTURERS			10. Additional Manufact	turer Narrative an	d / or 11. Corrected Data
1. Contact Office (and	Manufacturing Site	e for Devices)	2. Phone Number			
Name		151				
			3. Report Source			
Address			(Check all that apply)			
			Foreign			
			Study			
Email Address			Consumer			
0			Health Professional			
Compounding Outsour		Yes	User Facility			
4. Date Received by Manufacturer (dd-mr	mm-yyyy) 5.	NDA#	Company Representa ive			
		IDA#	Distributor			
6. If IND, Give Protocol	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	IND #	Other:			
,,		BLA #				
	P	MA/				
7. Type of Report (Check all that apply)		0(k) #	·			
5-day 30-da		mbination				
7-day Perio	dic	Product Product				
10-day Initial	L I	Pre-1938 Yes	· · · · · · · · · · · · · · · · · · ·			
	w-up #	OTC Yes				
9. Manufacturer Repor	t Number 8 Ad	verse Event Term(s)				
J. manufacturer repor	o. Ad	verse Lvent renn(S)				
This section applie	s only to requirem	ents of the Paperwor	k Reduction Act of 1995.	Department of Health and Hun	nan Services	OMB Statement: "An agency may not

The public reporting burden for his collection of information has been estimated to average 73 minutes per response, including he time for reviewing instructions, searching existing data sources, ga hering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collec ion of information, including suggestions for reducing this burden to:

conduct or sponsor, and a person is not required to respond to, a collection of informa ion unless it displays a curren ly Food and Drug Administration Office of Chief Information Officer Paperwork Reduc ion Act (PRA) Staff PRAStaff@ida.hhs gov valid OMB control numt Please DO NOT RETURN this form to the above PRA Staff email address. valid OMB control number.

(CONTINUATION PAGE)
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MEDWATCH FORM FDA 3500A (10/15) (continued)

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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

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

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

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

Page 5 of 5

UF/Importer Report # 0533050000-2023-8014

Other Remarks (For continuation of B5)

MEDWATCH

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 Manager of **(b)(6)** , found findings consistent with ours at the 50 mL, 100 mL, 120 (b) (6) 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

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