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 3500
Priority	High		
Override Auto Calculation Rule	No		
FDA Received Date	14-Jul-2023	CTU Received Date	14-Jul-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)			

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b) (6)
	Age	
	Date of Birth	10-Apr-2023
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Weight	0.81 kg
	Ethnicity (Check single best answer)	Not Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaska Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

	Type of Report (check all that apply)	☑ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
	Serious	Yes
	Outcome Attributed to Adverse Event (Check all that apply)	☑ Death ☐ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	27-Apr-2023
Date of Event	27-Apr-2023
Date of this Report	14-Jul-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: 24 week premature birth given neonatal Bifidobacterium Infantis 0.04 gram (8 bill cell/0.5mL Oral Liquid 0.5 mL (EVIVO WITH MCT OIL). Sepsis developed with probiotic strain above cultured.

Relevant Test/Laboratory Data 1 of 1

Test Name	BACTERIAL RDNA SEQUENCING	Test Date	17-Apr-2023
Test Result	genetically consistent with bifidobacterium longum	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

premature birth

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S) 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report involves:	Dietary Supplement

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Bifidobacterium Infantis (8 bill cell/0.5mL Oral Liquid) EVIVO MCT oil		
Strength		If Other	
Manufacturer/Compounder	Evivo		

NDC# or Unique ID	no NDC
Product Type(check all that apply)	☑ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	No
Event Reappeared after Reintroduction ?	Doesn't Apply

Drug Therapy 1 of 1

Dose or Amount	0.04 G gram(s)	If Other	
Frequency	Daily	If Other	
Route	Oral	If Other	
Dosage Form			
Start	13-Apr-2023		
Stop	25-Apr-2023		
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

prematurity

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	
If Implanted, Give Date	

If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

1 of 1

Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b) (6)		
Middle Name			
First Name	(b) (6)		
Address			
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b) (6)		
Phone			
Email			
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Pharmacist	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	No		