United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 08/19/2016

COMPLAINT	# 127882

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
08/27/2012	FLA-DO	FLA-DO	Letter	Friend/Relative of Consumer	Bennett,Robert B	Closed

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complainant filed complaint about suspected unethical practices while participatin in a bone marrow transplant clinical trial for children with genetic diseases conducted in 1996, which resulted in cortical blindness. loss of hearing and mental status suspected due to use of Cyclosporin A. Complainant is concerned that the sibling (donor) was told that it would make a difference, but only succeeded in entering them into the study Complainant further claims that she was never advised that this bone marrow transplant would activate Adrenoleukodystrophy in order to observe a bone marrow transplant.	Non-Life Threatening Injury/Illness		

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	08/27/2012					

Remarks

Study Name is : (b) (4)

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Blindness	NERVOUS	11 Days	Persists	Adverse event from Cyclosporin A
Change in hearing	NERVOUS			loss of hearing

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
	Medical Study	57NH-03	Cell Therapies;Final Product; Ready For Use	42R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
				No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			No		

Retail

Name	Address

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)	(b) (6)	FLA-DO	Clinical Investigator/Animal Clinical Investigator

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Other, identify in Details	Unethical Practices

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Bennett,Robert B	08/27/2012

Initial Disposition Remarks

Refer to CDER OC/Bimo

Referrals

Org Name	HHS Mail Code
CBER	HFM-1

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition **Disposition Made By** **Disposition Date**

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code