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	# 144501

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/03/2016	FLA-DO	FLA-DO	Telephone	Company Employee	Milan,Stephanie C	Closed

Complainant Identification

Name	Address
Anonymous	University of Florida Cancer Center, 1400 S. Orange Ave., MP-7600, Orlando, FL 32806

Phone (W)	Phone (H)	Source POC Name	Source Phone
N/A	Unknown	Anonymous,	Unknown

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 02/08/16, FLA-DO, BIMO Specialist, CSO Brunilda Torres forwarded through e-mail, an anonymous industry complaint, which is abridged in part as follows: On 2/3 and 2/5/2016, CSO Brunilda Torres, spoke over the phone with a member of the (b) (6) staff at the University of Florida Cancer Center (formerly known as the Anderson Cancer Center), located in Orlando FL. The anonymous complainant express concerns related to the study titled (b) (4) which was audited during a "For Cause Inspection" conducted under FACTS Assignment # (b) (4) Please refer to EIR of (b) (6) (b) (6) dated (b) (4) -FEI # (b) (6)). The above referenced inspection, was initiated as a follow-up, to issues on GCP non-compliance, which occurred at the UF Cancer Center, and prompted the Orlando Health IRB to close the (b) (4) study. This inspection disclosed serious GCP non-compliance concerns, that includes the research activities being conducted at the cancer center, the Office of Corporate Research Operations and Orlando Health IRB. As such, the decision to suspend enrollment activities in all studies at the cancer center and the closing of three studies, which included the (b) (4) study. The (b) (4) study was initially placed on administrative hold and later closed by the IRB, after becoming aware of an internal audit, which disclosed outstanding issues with source documentation for protocol, required visits, and SAEs. The study was conducted under IND (b) (4) Please see continuation in "Remarks"	None		

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No		N/A	N/A	N/A	Not Report to Other Source	No

Remarks

Continuation from "Complaint Description"

The anonymous complainant was contacted by an independent legal investigator, who reported, that a lawsuit had been filed against the firm, for having received misleading study results, which were filed by the financial investors of (b) (4) (b) (4) (sponsor of the (b) (4) study).

This was verified as per an article on (b) (4) . (b) (4)

Additionally, the article reports that the company made allegedly false and/or misleading statements and/or allegedly failed to disclose that the claims regarding positive results from the (b) (4) study were based on preliminary and unconfirmed trial results. The article also reports that on (b) (4) , the MD Anderson Cancer Center issued a stern rebuke to (b) (4) for making promotional, unjustified claims about results from an ongoing clinical trial of an experimental (b) (4) known as (b) (4) and that on (b) (4) , the (b) (4) trial in (b) (4) was temporarily halted.

Furthermore, the anonymous complainant reported that as part of the corrective actions implemented at the UF Cancer Center Research site, a review of the raw data collected during the (b) (4) study was initiated. Upon discovering errors on tumor readings of CT images taking from the study participants, the images were re-submitted to the Radiology Department for a second reading. Some of the initially reported tumor measurements data used to establish disease progression was changed. The revisions made to the initially reported values occurred subsequent to the FDA inspection, dated 4/2/2015.

Please see continuation in "Initial Disposition Remarks"

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks

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
(b) (4) ,	(b) (4)	(b) (4)	Cell Therapies;Final Product; Ready For Use	42R801	N/A

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

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
N/A	N/A	N/A	No	Unknown Country Complaints Use Only	N/A

Retail

Problem Ingredient Group

Name	Address
University of Florida Cancer Center,	1400 S. Orange Avenue, MP-760, Orlando, FL 32806

Manufacturer/Distributor

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

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Other, identify in Details	Unethical and serious GCP non-compliance concerns with the (b) (4) study .

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Surveillance Information for Next EI	Milan,Stephanie C	02/08/2016

Initial Disposition Remarks

The responsible firm identified as per CSO B. Torres

Continuation from "Remarks"

The anonymous complainant expressed concern with the implication of the revised tumor measurement, could have on the overall study data and the results, which were initially reported by the sponsor ((b) (4)) to the FDA.

The anonymous complainant reported that because of the restrictions imposed by the IRB to the site, the center's staff were not allowed to enter data into the study database. The institution's research department allowed staff from the CRO, which was contracted by the sponsor, to enter the data into the study database. The sponsor monitor, who was the one closeing and certify the entered data. Furthermore, during the review of some these (b) (4) some errors were discovered, but were corrected.

The anonymous complainant expressed concerns with the design of the trial that in some cases would require the participating subjects, to go without treatment, for up to three months.

The anonymous complainant reported that an investigation has been initiated by (b) (4) regarding a conflict of interest, between the sponsor's CEO (b) (4) (b) (4), the company that manufactures the study (b) (4)

Referrals

Org Name	**HHS Mail Code**
CBER-DIS	HFM-650

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