

**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

<b>COMPLAINT</b>	<b># 131004</b>
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Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/22/2013	LOS-DO	LOS-DO	Telephone		Lee, Franklin	In Progress - Pending Evaluation

**Complainant Identification**

Name	Address
Anonymous Informant	(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
Anonymous Informant (AI) report biomed company storing, processing cord blood stem cells in questionable environment and non-compliant to cGMPS. AI described area had heavy black mold growth, rodent infestation, and in processing lab, water leakage. Facility inspected 2011.	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	Yes

**Remarks**

**Complaint Symptoms**

Symptom	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
Stemcyte	Cord Blood Therapeutics	57NH-03	Cell Therapies;Final Product; Ready For Use	42R801	n/a

<b>Qty / Unit / Package</b>	<b>Lot/ Serial #</b>	<b>Exp/Use by Date</b>	<b>Purchase Date</b>	<b>Product Used</b>	<b>Amount Consumed/Used</b>
	n/a	n/a	n/a	No	n/a

<b>Date Used</b>	<b>Date Discontinued</b>	<b>Amount Remained</b>	<b>Imported Product?</b>	<b>Country of Origin</b>	<b>Label Remarks</b>
n/a	n/a	n/a	No		

**Retail** **Problem Ingredient Group**

**Name** **Address**

**Manufacturer/Distributor**

<b>FEI</b>	<b>Name &amp; Address</b>	<b>Home District</b>	<b>Firm Type</b>
3003562296	StemCyte, Inc 1589 W Industrial Park St Covina California United States 91722-3416	LOS-DO	Blood Banks

**Initial Evaluation/Initial Disposition**

<b>Problem Keyword</b>	<b>Problem Keyword Details</b>
Other, identify in Details Filtr	failure to comply with cGMPs mold growth, rodents

<b>Initial Evaluation</b>	<b>Initial Disposition</b>	<b>Disposition Made By</b>	<b>Disposition Date</b>
FDA Action Indicated	Immediate Follow-Up	Lee, Franklin	03/01/2013

**Initial Disposition Remarks**

Assignment #1499354 issued. LOS-DO CSO G. Arcy following this complaint.

**Referrals**

<b>Org Name</b>	<b>HHS Mail Code</b>
LOS-DO	HFR-PA200

**There are no Cosmetics details for this Complaint.**

**There are no Adverse Event details for this Complaint.**

**COMPLAINTS FOLLOW - UP**

**Grouped Follow - Up Operations**

<b>Operation Id</b>	<b>Operation Code</b>	<b>Assignment Number</b>	<b>Accomplishing Organization</b>	<b>Performing Organization</b>	<b>Sample Number</b>	<b>PAF</b>	<b>Status</b>	<b>Status Date</b>
6634459	12	1499354	LOS-DO	LOS-IB-VL			Completed	06/21/2013

**Disposition Summary**

<b>Is Consumer Responsible?</b>	<b>Responsible FEI</b>	<b>Address</b>	<b>Name</b>	<b>Firm Type</b>
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<b>Follow-Up Disposition</b>	<b>Disposition Made By</b>	<b>Disposition Date</b>
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**Disposition Remarks**

**Follow-Up Sent To**

<b>Organization Name</b>	<b>HHS Mail Code</b>
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