

**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># 141021</b>
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Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
04/03/2015	DEN-DO	FLA-DO	Telephone	Company Employee	Chastagner,Stephanie C	Closed

**Complainant Identification**

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

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

**Complaint/Injury**

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
The manufacturer/dist is making medical for a cosmetic that contains Human stem cells, making this an un-approved new drug.	None		

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No						

**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
Jeunesse Global	Luminesce	57NH-03	Cell Therapies;Final Product; Ready For Use	46R801	All

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
Ounces Jar	All	All	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	United States	

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

**Name** **Address**

**Manufacturer/Distributor**

<b>FEI</b>	<b>Name &amp; Address</b>	<b>Home District</b>	<b>Firm Type</b>
3008349990	Jeunesse Global 650 Douglas Ave Altamonte Springs Florida United States 32714-2593	FLA-DO	Manufacturer

**Initial Evaluation/Initial Disposition**

<b>Problem Keyword</b>	<b>Problem Keyword Details</b>
Other, identify in Details	Medical claims on un-approved new drug/using adult human stem cells in OTC cosmetic

<b>Initial Evaluation</b>	<b>Initial Disposition</b>	<b>Disposition Made By</b>	<b>Disposition Date</b>
FDA Action Indicated	Referred to Other FDA District	Chastagner,Stephanie C	10/28/2015

**Initial Disposition Remarks**

**Referrals**

<b>Org Name</b>	<b>HHS Mail Code</b>
FLA-DO	HFR-SE200

**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
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There are no Follow Up Operations related to this complaint.

**Disposition Summary**

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	3008349990	650 Douglas Ave Altamonte Springs Florida United States 32714-2593	Jeunesse Global	Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Milan,Stephanie C	11/02/2015

**Disposition Remarks**  
 F/U Next EIR. (SSM 11/02/15)

**Follow-Up Sent To**

Organization Name	HHS Mail Code
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