

**United States Food and Drug Administration  
Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 11/01/2012

**COMPLAINT # 98905**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
09/17/2009	ATL-DO	NWE-DO	Letter	Consumer	[REDACTED]	Closed

**Complainant Identification**

Name	Address
A concerned citizen of North Carolina	NC

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

**Complaint/Injury**

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
As reported by concerned citizen "...as a concerned citizen of the state of North Carolina I am taking this opportunity to inform the members of the medical board that there is a physician here in [REDACTED] NC that its using a non-FDA approved medication for the treatment of varicose and spider veins. This medication, sodium tetradecyl sulfate, is being obtained by that physician at an out-of-state compounding pharmacy...I am very concerned that the health and well-being of patients seeking treatment for varicose and spider veins in North Carolina is being compromised by this...	None		

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

<b>Brand Name</b>	<b>Product Name</b>	<b>Product Code</b>	<b>Product Description</b>	<b>PAC</b>	<b>UPC Code</b>
	Sodium tetradecyl sulfate	55PA-71	Sodium Stearate (Pharmaceutic Necessity - Emulsifying & Stiffening Agent); Closure Liners&Seals	56R801	

<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>
				No	

<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>
			No		

**Retail**

**Problem Ingredient Group**

<b>Name</b>	<b>Address</b>
NECC New England Compounding Center	697 Waverly Street Framingham MA 01702

**Manufacturer/Distributor**

<b>FEI</b>	<b>Name &amp; Address</b>	<b>Home District</b>	<b>Firm Type</b>
3003623877	New England Compounding Center 697 Waverly St Framingham Massachusetts United States 01702-8589	NWE-DO	Manufacturer

**Initial Evaluation/Initial Disposition**

<b>Problem Keyword</b>	<b>Problem Keyword Details</b>
Other, identify in Details	unapproved use of drug

<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		09/17/2009

**Initial Disposition Remarks**

PDF attachment to home district of retail establishment.

**Referrals**

<b>Org Name</b>	<b>HHS Mail Code</b>
NWE-DO	HFR-NE200

**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	3003623877	697 Waverly St Framingham Massachusetts United States 01702-8589	New England Compounding Center	Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	[REDACTED]	10/01/2009

**Disposition Remarks**

A letter from the consumer and an article titled "Compounded Sclerosing Agents: Risks and Consequences" is attached to the complaint file. The consumer is concerned that the compounding pharmacy is mass-producing this drug instead of on a case-by-case basis. NWE-IB notified NWE-CB. NWE-CB consulted with CDER, Samia M. Nasr, R.Ph., M.S. Team Leader, Division of New Drugs and Labeling Compliance. CDER is aware of [REDACTED] and NECC compounding sodium tetradecyl sulfate and will be issuing an assignment for NECC in the future. Follow-up at next EI.

**Follow-Up Sent To**

Organization Name	HHS Mail Code
NWE-IB	HFR-NE250