

[REDACTED]

From: [REDACTED]
Sent: Monday, September 28, 2009 3:17 PM
To: [REDACTED]
Subject: FW: CC 98905 New England Compounding Center
Attachments: CC 98905 NECC Letter.pdf

[REDACTED]

NWE-DO received this complaint from ATL-DO for potential follow-up. [REDACTED] mentioned that you may be working on some action already in process for NECC.

Do you suggest we follow-up to this complaint immediately, or wait until the next inspection?

There is one unanswered question about this complaint. Unfortunately, the letter does not mention if the consumer asked NECC for Sodium tetradecyl sulfate with alteration or without. The letter states that when the consumer called NECC and asked for pricing, the NECC rep gave it to her over the phone. The consumer believes it is readily available to anyone who wants to buy it.

[REDACTED]

Consumer Complaint Coordinator
New England District Office
U.S. Food and Drug Administration

Phone: [REDACTED]

Fax: [REDACTED]

From: [REDACTED]
Sent: Thursday, September 24, 2009 3:40 PM
To: [REDACTED]
Subject: CC 98905 New England Compounding Center

[REDACTED]

We received the attached complaint about New England Compounding Center (NECC), in Framingham (FEI 3003623877).

The Complainant is from North Carolina and stated in a letter that NECC is selling Sodium tetradecyl sulfate for treating varicose and spider veins. Complainant alleges there is only one brand name prescription drug on the market called Sotradecol and made by Bioniche Pharmaceuticals. Complainant alleges the only reason a doctor would use compounded sotradecol in lieu of the branded product is to save money. Sotradecol is reportedly very expensive costing \$20 per ml of 3% solution, where as sotradecol from NECC is a fraction of that cost. The complainant claims to have received pricing from [REDACTED] at NECC. 30 ml of 3% Sotradecol = \$2.50 per ml.

Complainant provided evidence (a medical record) that sodium tetradecyl sulfate is being obtained from NECC by an out of state physician in NC.

According to [REDACTED] this firm has a past history. How do you suggest we proceed? Is there an assignment for FEI 3003623877 for FY 2010?

Should we create an immediate follow-up OP 12 assignment? Contact the State, Board of Pharmacy??

[REDACTED]
Consumer Complaint Coordinator

New England District Office

U.S. Food and Drug Administration

Phone: [REDACTED]

Fax: [REDACTED]