



The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JAN 16 2009

Dear Mr. Barton:

Thank you for your letter of December 10, 2008, requesting information in connection with the seizure of 11 lots of heparin at Celsus Laboratories, Inc. in Cincinnati, Ohio on November 6, 2008.

We have restated your questions below in bold, followed by the Food and Drug Administration's (FDA or the Agency) response. The responses are limited in some respects because this is currently an open matter before the court. When the case is closed, the Agency will be able to provide more complete information.

1. Why did FDA wait until November 2008 to seize the contaminated lots?

This case is a complex matter involving both drugs and medical devices, the review of inspectional evidence, clinical health assessments for various drugs and medical device products, as well as sampling and analyses by FDA laboratories. An in rem seizure is a serious regulatory action that proceeds in federal court and can take considerable time and coordination both within FDA and with the Department of Justice and the U.S. Marshals Service. In this case, FDA informed Celsus Laboratories during an April 2008 inspection and again in a letter dated May 8, 2008, that the company's actions to notify customers about a contaminant in its heparin were insufficient to ensure an effective recall. Initially, FDA made attempts to negotiate with the firm to obtain voluntary compliance that fully addressed the contaminant concerns. Once it became clear that Celsus would not conduct an effective recall, FDA began the process of determining whether a seizure was the appropriate enforcement action. Celsus agreed that it would quarantine the contaminated heparin products at its facility and not distribute them into commerce during this time.

Following the procedures outlined in FDA's Regulatory Procedures Manual (attached at Tab A), the Agency reached consensus to request that the U.S. Attorney for the Southern District of Ohio file a Verified Complaint for Forfeiture In Rem. The United States Attorney makes the final decision to initiate an in rem seizure. In this case, after the Complaint was filed (a copy is enclosed at Tab B), the warrant issued and the U.S. Marshals Service was asked to effectuate the seizure.

2. When was the recommendation to seize this contaminated heparin first made? Who made it? Was it a written recommendation? Please provide supporting records as appropriate.

The Agency is limited in the information that can be shared as the matter is currently pending before the court. We are enclosing public documents that include: a copy of the FDA press release (Tab C), the redacted List of Observations, Form 483 (Tab D), and a copy of the Verified Complaint for Forfeiture In Rem (Tab B).

3. Please provide all FDA regulations, policies, and/or guidelines that govern the standards for authorizing this type of seizure.

Seizure actions are in rem proceedings explicitly authorized under the Federal Food, Drug, and Cosmetic Act, 21, U.S.C. § 334, and subject to the Supplemental Rules for Certain Admiralty and Maritime Claims of the Federal Rules of Civil Procedure. Ordinarily, the U.S. Marshals Service publishes notice of the action and seizure of the articles according to the supplemental rules and consistent with the instructions set forth in the warrant of arrest. FDA guidelines for recommending and approving seizure actions are set forth in Chapter 6 of the Regulatory Procedures Manual (attached at Tab A).

4. Please list the names, titles, and offices of the FDA officials involved in the recommendation for the seizure of the contaminated heparin.

This is an open matter before the court, and as such, we cannot provide the names of employees other than those that have already been made public.

5. Please list the names, titles, and offices of the FDA officials involved in the decision on whether to approve the recommendation for seizure.

This is an open matter before the court, and as such, we cannot provide the names of employees other than those that have already been made public.

Thank you again for your interest in this matter. Please contact us if you have further questions.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

cc: The Honorable John Dingell, Chairman
Committee on Energy and Commerce

The Honorable Frank Pallone
Chairman
Subcommittee on Health

The Honorable Nathan Deal
Ranking Member
Subcommittee on Health

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

The Honorable John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations