

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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

APR 28 2009

Dear Mr. Barton:

Thank you for your letter of December 10, 2008, requesting information regarding the seizure of 11 lots of heparin at Celsus Laboratories, Inc. in Cincinnati, Ohio, on November 6, 2008, by the Food and Drug Administration (FDA or the Agency). On January 16, 2009, we provided an initial response with limited answers to questions # 2, # 4, and # 5, because the case was an open matter before the court. We are providing more complete information to these questions because the case is now closed.

We have restated the requests below in bold, followed by our responses.

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.

Charles Ahn, Consumer Safety Officer, Division of Compliance Management Operations, Office of Regulatory Affairs sent a written recommendation to seize the contaminated heparin to Eric M. Blumberg, FDA's Deputy Chief Counsel for Litigation on September 15, 2008. FDA's Office of the Chief Counsel approved the recommendation on September 19, 2008.

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

The following Agency officials were involved in the recommendation to seize heparin at Celsus Laboratories, Inc., based on the input of their staff:

- Annamarie Kempic, Associate Deputy Chief Counsel for Litigation
- Eric M. Blumberg, Deputy Chief Counsel for Litigation
- Frederic Richman, Director, Division of Compliance Management Operations, Office of Enforcement, Office of Regulatory Affairs
- Joseph Famulare, Deputy Director, Office of Compliance, Center for Drug Evaluation and Research
- Timothy A. Ulatowski, Director, Office of Compliance, Center for Devices and Radiological Health

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- **Toniette K. Williams, Director, Compliance Branch, Cincinnati District Office, Office of Regulatory Affairs**

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

The same officials listed in our response to question # 4 were involved in the decision on whether to approve the recommendation for seizures.

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**

cc: **The Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce**

**The Honorable Frank Pallone
Chairman
Subcommittee on Health**

**The Honorable Nathan Deal
Ranking Member
Subcommittee on Health**

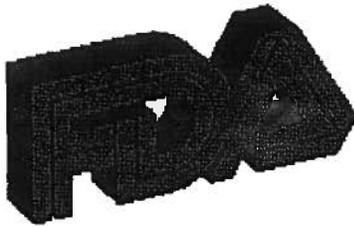
**The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations**

**The Honorable Greg Walden
Ranking Member
Subcommittee on Oversight and Investigations**

**The Honorable John Dingell
Committee on Energy and Commerce**

**The Honorable John Shimkus
Committee on Energy and Commerce**

TELEFAX TRANSMITTAL SHEET



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DATE: April 28, 2009

TO: Alan Slobodin	FAX NUMBER: 202-225-1919
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FROM:	Heather Rubino Althouse (301-827-5211), FDA, OL
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COMMENTS:	<p>Hi, Alan,</p> <p>Following is FDA's follow-up response to Rep. Barton's Dec. 10, 2008 letter regarding Celsius Laboratories.</p> <p>Heather</p>
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