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ONE HUNDRED TENTH CONGRESS

**U.S. House of Representatives**  
**Committee on Energy and Commerce**  
**Washington, DC 20515-6115**

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March 12, 2008

DENNIS B. FITZGIBBONS, CHIEF OF STAFF  
GREGG A. ROTHSCCHILD, CHIEF COUNSEL

Mr. David Strunce  
Chief Executive Officer  
Scientific Protein Laboratories, LLC  
700 East Main Street  
Waunakee, WI 53597-0158

Dear Mr. Strunce:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the ability of the Food and Drug Administration (FDA) to protect the American public from excessive risks associated with prescription drugs. As part of this investigation, we are looking into the February 28, 2008, recall of heparin by Baxter International, Inc.

We understand that Baxter International, Inc. purchased the active ingredient for their recalled heparin products from Scientific Protein Laboratories, LLC and that the raw heparin ingredients, at least in substantial part, were manufactured in China. We are concerned that the regulatory framework to protect American patients from the ill effects of contaminated pharmaceutical products may be ineffective.

Therefore, we ask that you provide the following:

1. The names, addresses, principal officers, and contact information for all suppliers of raw heparin products to Scientific Protein Laboratories, LLC since 2002;
2. All FDA Establishment Inspection Reports (EIRs) and form 483s related to Scientific Protein Laboratories, LLC and any supplier of raw heparin products since 2002;
3. All FDA warning letters related to Scientific Protein Laboratories, LLC and any supplier of raw heparin products since 2002;

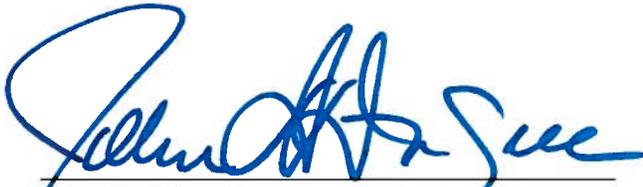
Mr. David Strunce  
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4. All records of communications between Scientific Protein Laboratories, LLC and Baxter International, Inc. since 2002;
5. All records of communications between Scientific Protein Laboratories, LLC and each of its raw heparin suppliers since 2002; and
6. All records of communications between Scientific Protein Laboratories, LLC and FDA since 2002.

Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records and/or staff interviews with company officials.

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact us or have your staff contact David Nelson or Christopher Knauer of the Committee Majority staff at (202) 226-2424.

Sincerely,



John D. Dingell  
Chairman



Bart Stupak  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member  
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member  
Subcommittee on Oversight and Investigations

## ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.