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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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April 30, 2008

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GREGG A. ROTHSCCHILD, CHIEF COUNSEL

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply. The recent outbreak of *Salmonella* associated with cantaloupe grown and packed in Honduras is of particular interest in this investigation.

On March 22, 2008, FDA announced its issuance of an import alert regarding entry of cantaloupe from Agropecuaria Montelibano, after fruit from the company was associated with a *Salmonella* Litchfield outbreak in the United States and Canada. According to the Centers for Disease Control and Prevention, at least 51 people in 16 States became ill, and 14 of these people were hospitalized, after eating cantaloupe contaminated with *Salmonella* grown and packed in Honduras by Agropecuaria Montelibano. To date, at least 10 American companies have issued recalls of cantaloupe produced by Agropecuaria Montelibano.

The problem of *Salmonella*-tainted cantaloupe is hardly a new phenomenon. Since 2005, there has been at least one recall of imported cantaloupe each year due to *Salmonella* contamination. This recurrence underscores FDA's inability to prevent this problem, and Americans continue to become ill as a result. It serves as another example of FDA's difficulties in protecting Americans from unsafe imports.

In order to assist the Committee in its investigation into the adequacy of the efforts of FDA to protect the safety of the Nation's food supply, we request that you provide the Committee with the following information:

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1. All Establishment Inspection Reports (EIRs) or 483s relating to inspections and/or sampling done by FDA regarding imported cantaloupe since January 1, 2002;
2. All EIRs or 483s relating to inspections and/or sampling done by FDA regarding Agropecuaria Montelibano or Agropecuaria Montelibano products since January 1, 2002;
3. Copies of all records of laboratory analyses from either FDA laboratories or private laboratories that have submitted results to FDA relating to analyses of imported cantaloupe or any imported Agropecuaria Montelibano product since January 1, 2002;
4. How and when FDA first become aware of this outbreak of *Salmonella* contamination of Agropecuaria Montelibano cantaloupe;
5. Where and when the *Salmonella* contamination was first detected;
6. Identify and describe the source of the contamination;
7. Describe the last instance in which Agropecuaria Montelibano's fields and processing facilities were inspected by FDA—providing the dates of such inspections and the names of the officials, as well as all records associated with those inspections and ongoing inspections;
8. Please provide all records relating to such inspections of Agropecuaria Montelibano's fields and processing facilities since January 1, 2002; and
9. Future steps FDA will take to ensure the safety of imported cantaloupe.

Please note that, for the purpose of responding to the above request, the terms “records” and “relating” should be interpreted in accordance with the attachment to this letter. Please supply all requested information no later than the close of business two weeks from the date of this letter. After review of your response and the requested records, we may require additional documents and/or staff interviews of FDA personnel.

If you have any questions relating to this request, please contact David Nelson or Kevin Barstow with the Committee staff at (202) 226-2424.

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Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

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.