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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

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
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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.

On April 11, 2008, the Centers for Disease Control and Prevention (CDC) released more discouraging news regarding the safety of this country's food supply. CDC reported that day, based on information gathered from its Foodborne Diseases Active Surveillance Network, that there has not been a significant decline in the incidences of foodborne illnesses since 2004—further proof that FDA is failing in its mandate to protect Americans from unsafe food. It is clear that FDA's efforts to improve this country's food safety system have failed.

While Americans have been forced to live with the consequences of a broken food safety system, it appears that FDA has taken little or no action in deciding whether to allow food irradiation—a technology that could increase the safety of the Nation's food supply. Food irradiation is a technology, approved for many uses in approximately 36 countries, that destroys organisms that cause foodborne illness. In the United States, FDA regulates all aspects of irradiation, and while FDA permits irradiation for pathogen reduction in meat and poultry and insect control in fruits and vegetables, FDA has not approved irradiation for many other foods. Currently, there are several petitions at FDA seeking the approval of irradiation for certain foods that have been languishing for years.

Perhaps the most important petition that FDA has failed to act upon is one submitted to FDA in 1999 that requested utilizing food irradiation to reduce pathogens in fruits and vegetables and other ready-to-eat foods. This petition requested that irradiation be used on fresh produce, such as leafy greens, to eliminate pathogens such as *Escherichia coli* (*E. coli*). Other food irradiation petitions that continue to await FDA action include two petitions from the United States Department of Agriculture, which were supposed to be reviewed on an expedited basis. More than eight years later, FDA has yet to issue a decision regarding any of these petitions. Further, there is evidence that FDA has taken little or no action on these petitions and does not plan to do so in the future. FDA's inaction is even more perplexing given that both the CDC and FDA have stated that food irradiation is a safe and effective technology that can prevent foodborne diseases.

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:

1. Please list all petitions seeking the approval of irradiation for certain foods submitted to FDA since January 1, 1999.
2. Please describe what action FDA has taken on each petition seeking the approval of irradiation for certain foods submitted to the agency since January 1, 1999.
3. Please provide all records relating to petitions seeking the approval of irradiation for certain foods submitted to the agency since January 1, 1999.
4. Describe when FDA plans to issue a final decision on each petition seeking the approval of irradiation for certain foods submitted to the agency since January 1, 1999.

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.

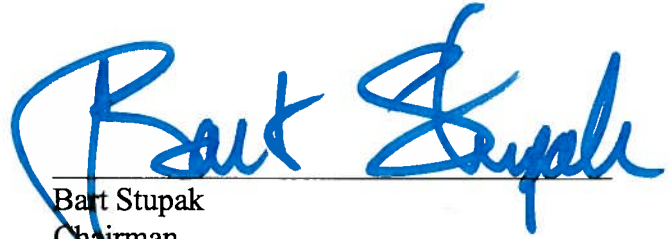
If you have any questions relating to this request, please contact Kevin Barstow with the Committee staff at (202) 226-2424.

The Honorable Andrew C. von Eschenbach, M.D.
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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.