ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

October 1, 2007

Julie Louise Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Atlanta, GA 30333

Dear Dr. Gerberding:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations have been investigating the human health consequences of antimicrobials administered to food animals. We are seeking your views on the continued indiscriminate use of animal antibiotics, which many experts believe is hastening the development of drug-resistant diseases.

On April 18, 2007, we sent a letter to Commissioner von Eschenbach of the Food and Drug Administration (FDA) requesting that FDA reconsider its approach to regulation of the use of certain antibiotics of last resort in food-producing animals. The dismissive response we received from FDA on June 5, 2007, leads us to conclude that the FDA appears more focused on protecting the interests of industry than in protecting human health. We need to know if the Centers for Disease Control and Prevention (CDC) shares the same views expressed in the June 5th letter from FDA (attached).

Additionally, we are concerned that FDA is considering the approval of one or more third or fourth generation cephalosporins for use in animals that are part of the American food supply. FDA's policy regarding this is inconsistent with public health and with expert opinion at the World Health Organization, the American Medical Association, the American Public Health Association, and the Infectious Disease Society of America (see attachment). Further, countless editorials in newspapers throughout the Nation urge disapproval of the use of cefquinome in animals and reflect informed opposition by much of the American public.

As the Nation's premiere health promotion and prevention agency, CDC should have developed a comprehensive and independent analysis of the relationship between antimicrobial resistance and antibiotic use in food animals. We further seek to learn the views of CDC on any

new animal drug application (NADA) for third and/or fourth generation cephalosporins. Accordingly, we request that you provide the Committee the following documents within three weeks of the date of this letter:

1. Any and all records that reflect analysis by CDC, or any office or division thereof, of the use of third and/or fourth generation cephalosporins in food animals;

2. Any and all records that reflect communications between CDC, or any office or division thereof, and the FDA, the FDA Office of Chief Counsel, or elsewhere within the Department of Health and Human Services, relating to any NADA for third and/or fourth generation cephalosporins; and

3. Any and all records reflecting communications between CDC, or any office or division thereof, and the FDA, the FDA Office of Chief Counsel, or elsewhere within the Department of Health and Human Services, relating to updating Appendix A of Guidance #152 by placing fourth generation cephalosporins in the higher "critically important class."

We appreciate your cooperation in this investigation. Please deliver copies of the requested records to the Committee on Energy and Commerce, U.S. House of Representatives, Room 316 Ford House Office Building, by no later than 21 days from the date of this letter. Please note that for the purpose of responding to this request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records.

If you have any questions regarding these requests, please contact us or have your staff contact David Nelson or Joanne Royce with Committee 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 Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Michael O. Leavitt, Secretary
U.S. Department of Health and Human Services

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.