DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 7, 2002

Mr. Bruce Silverglade
US Co-Chair, Food Working Group
TACD Secretariat
24 Highbury Crescent
London N5 1RX, UK

Dear Mr. Silverglade:

I have been asked to respond to your letter addressed to Secretary Thompson regarding your concerns about the non-therapeutic and prophylactic uses, as well as certain therapeutic uses, of antibiotics in animals both in the United States and internationally. A similar letter has been sent to Ms. Davies.

The U.S. Food and Drug Administration (FDA) agrees that the availability of safe and effective antibiotics is critical for human medical therapy and that antimicrobial resistance is a serious global public health threat. In addressing the antimicrobial resistance problem, FDA's goal is to ensure that practitioners have a continuous supply of safe and effective antimicrobials available to protect the health of both humans and animals.

In 1999, an interagency Task Force on Antimicrobial Resistance was created that is co-chaired by the FDA, Centers for Disease Control and Prevention, and the National Institutes of Health. The Task Force also includes the United States Department of Agriculture, the Department of Defense, the Department of Veterans Affairs, the Environmental Protection Agency, and other health agencies. In January 2001, the task force published a Public Health Action Plan to Combat Antimicrobial Resistance (Action Plan). The Action Plan reflects a broad-based consensus of federal agencies on actions needed to address antimicrobial resistance. It provides a blueprint for specific, coordinated actions to address the emerging threat of antimicrobial resistance. This coordinated plan has both a domestic and international part. Part I of the Action Plan focuses on domestic issues. Part II of the Action Plan, to be developed in 2002, will identify actions that specifically address international issues.

The FDA also published a concept document to specifically address the issue of microbial effects associated with antimicrobial drug use in animals (the Framework Document). FDA expects to publish Guidance for Industry in the summer of 2002 to implement the concepts described in the Framework Document. FDA is also active in enhanced surveillance for detecting changes in susceptibility patterns for antibiotics as well as targeted research and the use of risk assessment to deal with this complex and evolving problem.

We recognize the need to coordinate and focus antimicrobial resistance activities with many other entities, both domestic and international. Currently, FDA engages in international consultations with many international organizations about antimicrobial use in food animals and the emergence of resistance. These organizations include the World Health Organization,

the Office of International Epizootics, the Codex Alimentarius Commission, and the Veterinary International Cooperation on Harmonization.

Despite your recommendation, the Agency cannot just ban the non-therapeutic and prophylactic use of antibiotics in animals. In this process, FDA has to first decide whether to initiate formal withdrawal proceedings and second, if FDA decides to initiate withdrawal proceedings, it must then undertake the formal withdrawal process required by statute. For legal, scientific and resource reasons, withdrawal actions need to be considered on a drug by drug basis. Data and information will need to be reviewed and analyzed for each drug. As mentioned previously, FDA is currently drafting guidance for industry that attempts to incorporate the various strategies/concepts discussed in the Framework Document in a single coordinated and comprehensive plan. The plan will include sections related to pre-approval product review, post-approval activities, and research, as well as a fourth section related to coordination and collaboration with other agencies and with stakeholders. The document will also provide information on FDA's regulatory process for re-evaluating currently approved antimicrobials to address microbial safety concerns.

In developing draft guidance for implementing the Framework Document, FDA is considering all relevant comments recorded at public meetings on the subject as well as all relevant comments received in writing. Your letter will be considered as we move forward. In addition, FDA intends to publish all guidance documents as drafts to seek additional public comment. Proposals for new or amended rules will be subject to a notice and comment rule-making process that will allow public input.

We welcome TACD's interest in our efforts to combat antimicrobial resistance. We look forward to working with you along with our other domestic and international stakeholders to successfully address this complex health problem.

Sincerely,

Murray M. Lumpkin, M.D.
Acting Deputy Commissioner