

**Congress of the United States**

Washington, DC 20515

11 28 '02 NOV 26 17:58  
November 26, 2002.

Dr. Mark McClellan  
Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

RE: Docket No. 98D-1146

Dear Dr. McClellan:

We are pleased that the FDA has drafted a guidance for industry on evaluating the safety and approval of new antimicrobial animal drugs. Given the rapid development of antimicrobial resistance from indiscriminate use of drugs in agriculture, we urge you to strengthen the guidance and to implement the recommendations in a rigorous manner to ensure that drugs vital for human medical needs remain effective for treating human illnesses.

Congress recognizes the problem of antimicrobial resistance as an important public health issue, as evidenced by the introduction of legislation during the 107<sup>th</sup> Congress pertaining to the non-therapeutic use of medically important antibiotics in farm animals. While the development of antimicrobial resistance is a complex phenomenon, it is clear that the widespread use of large amounts of antibiotics in agricultural animals is promoting selection for resistant organisms and contamination of our food and environment. The draft FDA guidance acknowledges this important public health concern and provides new methods of drug evaluation intended to ensure the continued availability of drugs used in human medicine.

To strengthen the guidance, we urge you to incorporate the following recommendations in the final document:

1. In addition to covering applications for new drugs, the FDA guidance should provide firm timelines and clearer guidance for the re-evaluation of currently approved drugs. We note that Appendix C of the Draft Guidance acknowledges the need, and outlines a proposed method, for re-evaluating the effects of currently approved drugs used in food-producing animals; however, neither a commitment nor timeline for this action is presented.
2. Given that resistance will likely develop with the use of any and all antimicrobial drugs, we urge the FDA to review rankings periodically – perhaps every three to five years. This would allow re-assessment and re-classification of the ranking of drugs based on up-to-date data. Additionally, guidelines should be included in the final document providing an expedited process for the withdrawal of a drug if at any time evidence indicates that such drug is contributing to increased resistance in human or animal pathogens, which presents a broad public health concern.

98D-1146

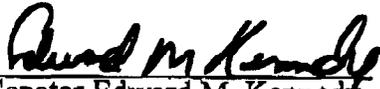
C 70

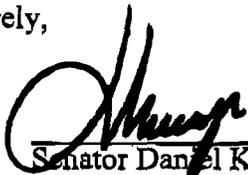
3. The FDA guidance document should also require manufacturers to collect production data on approved drugs and submit that data to the agency annually. Manufacturers should submit data on what drugs are used, for what purpose and in what particular species. This data will facilitate the tracking and monitoring of antimicrobial resistance development, and the reassessment of drugs. Antimicrobial resistance is a dynamic phenomenon and post-approval monitoring is critical to addressing the continued efficacy of antimicrobial drugs.

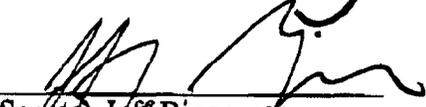
By adopting these recommendations, we believe the FDA would better protect drugs vital for human medical needs and provide clearer guidance to industry for the approval of antimicrobial animal drugs. We commend the FDA on its efforts to ensure that all drugs used therapeutically in humans or animals are used judiciously. We also commend the agency for its efforts to encourage research and development of innovative classes of antimicrobial agents. The FDA has a critical role to play in ensuring that safe and effective drugs remain as an available arsenal for the fight against infectious diseases.

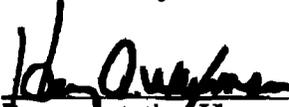
We look forward to your finalizing, as quickly as possible, the FDA's guidance to industry on evaluating the safety of antimicrobial new animal drugs, and we urge you to incorporate the recommendations outlined above. If it is not feasible for these recommendations to be addressed in the guidance document, we would appreciate the FDA's response as to how these concerns might best be dealt with. Thank you for your consideration and for undertaking this important effort.

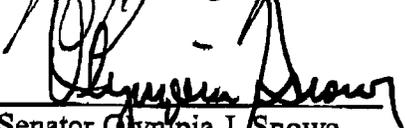
Sincerely,

  
 Senator Edward M. Kennedy

  
 Senator Daniel K. Inouye

  
 Senator Jeff Bingaman

  
 Representative Henry A. Waxman

  
 Senator Olympia J. Snowe

  
 Representative Louise M. Slaughter

  
 Senator Jack Reed

Cc:

Lester Crawford, D.V.M., PhD., Deputy Commissioner  
 Stephen Sundlof, D.V.M., PhD., Director, Center for Veterinary Medicine  
 Linda Tollefson, D.V.M., M.P.H., Deputy Director, Center for Veterinary Medicine  
 Dockets Management Branch, U.S. Food and Drug Administration

EDWARD M. KENNEDY  
MASSACHUSETTS

**UNITED STATES SENATE**  
**COMMITTEE ON HEALTH, EDUCATION,**  
**LABOR AND PENSIONS**

WASHINGTON OFFICE:

317 RUSSELL SENATE OFFICE  
BUILDING  
WASHINGTON, DC 20510-2101  
202.224.4543  
WWW.SENATE.GOV/~KENNEDY

CHAIRMAN:

HEALTH, EDUCATION,  
LABOR AND PENSIONS

SUBCOMMITTEE ON PUBLIC HEALTH

JUDICIARY SUBCOMMITTEE  
ON IMMIGRATION



BOSTON OFFICE:

2400A JOHN F. KENNEDY BUILDING  
BOSTON, MA 02203  
617.565.3170

COMMITTEES:

ARMED SERVICES  
JUDICIARY  
JOINT ECONOMIC

**EDWARD M. KENNEDY**  
**CHAIRMAN**

HEALTH OFFICE:

527 HART SENATE OFFICE BUILDING  
WASHINGTON, DC 20510-6300  
202.224.7675

**FACSIMILE TRANSMISSION**  
IF THIS FAX IS INCOMPLETE,  
PLEASE CALL 202.224.7675

TO: **DOCKETS MANAGEMENT BRANCH**  
FAX:  
FROM: **DR. PREMA ARASU**  
DATE: **11/26/02**

PAGES  
(INCL. COVER): **3**

**COMMENTS:**

Letter re: FDA "guidance to Industry"  
Docket # 98D-1146