

Lester Crawford, D.V.M
Acting Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
MS HF-1
Rockville, MD 20857

April 7, 2005

Dear Acting Commissioner Crawford,

We understand the Food and Drug Administration (FDA) today is receiving a Citizen Petition urging the Agency to withdraw approvals for nontherapeutic feed-additive use in agricultural animals of antibiotics that belong to the classes of antibiotics designated by the Agency as "highly important" or "critically important" in FDA Guidance #152 on agricultural antibiotics. As spelled out in the Petition, such use in chicken, swine, and beef cattle is inconsistent with the safety criteria established in the Agency's Guidance #152.

We write to urge you to respond quickly and positively to the petition. Antibiotic resistance is a serious and growing public-health threat, one exacerbated by overuse of antibiotics in agriculture. While such overuse also occurs in human medicine, we concur Institute of Medicine's recent observation that "Clearly, a decrease in the inappropriate use of antimicrobials in human medicine alone is not enough. Substantial efforts must be made to decrease inappropriate overuse of antimicrobials in animals and agriculture as well."¹

We recognize that FDA's procedures for contested withdrawals of existing drug approvals can take years, so we urge you to start that process for the uses covered by the Petition as soon as possible. As the World Health Organization recently noted, "Our grandparents lived during an age without antibiotics. So could many of our grandchildren."² In the interest of making that outcome less likely, we urge your expeditious implementation of the steps called for in the Petition.

Sincerely,

Michael Jacobson, Ph.D.
Executive Director
Center for Science in the Public Interest
1875 Connecticut Ave., NW, Suite 300
Washington, DC 20009

David Wallinga, M.D.
Director, Antibiotics Resistance Project
Institute for Agriculture and Trade Policy
2105 First Avenue South
Minneapolis, MN 55404

¹ Institute of Medicine, Board on Global Health (2003). **Microbial Threats to Health: Emergence, Detection, and Response**. National Academy of Sciences Press, Washington, DC, at page 207. Available at <http://books.nap.edu/books/030908864X/html/207.html#pagetop> (accessed Apr. 5, 2005)

² World Health Organization, World Health Organization Report on Infectious Diseases 2000: **Overcoming Antimicrobial Resistance**, Epilogue, available at <http://www.who.int/infectious-disease-report/2000/> (accessed Apr. 5, 2005).