



# American Public Health Association

*Working for a Healthier World*

800 I Street, NW • Washington, DC 20001-3710

(202) 777-APHA • Fax: (202) 777-2534 • [comments@apha.org](mailto:comments@apha.org) • [www.apha.org](http://www.apha.org)

April 2, 2007

The Honorable Andrew C. von Eschenbach, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner von Eschenbach:

I write on behalf of the American Public Health Association (APHA) to express APHA's concern about the potential approval by the Food and Drug Administration (FDA) of the use of a 4<sup>th</sup> generation cephalosporin to treat bovine respiratory disease. APHA is the nation's oldest, largest and most diverse organization of public health professionals in the world, dedicated to protecting all Americans, their families and their communities from preventable, serious health threats and assuring community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States.

Approval of the use of cephalosporin in animals could potentially increase resistance to 4<sup>th</sup> generation cephalosporins currently used in humans to treat pneumonia and resistant infections, especially in children and the elderly. That concern led to the FDA's own Veterinary Medicine Advisory Committee (VMAC) voting to reject drug manufacturer InterVet Inc.'s request to market cefquinome for use in cattle in the United States, because it was found 'not safe' for humans. The American Medical Association and the Infectious Disease Society of America (IDSA) are also opposed to the use of cefquinomes in cattle. In the interest of the public's health, APHA strongly urges you to follow the VMAC's recommendation and not approve cefquinome for animal use.

In 1995, FDA approved the use of Baytril, a fluoroquinolone, in poultry flocks. Fluoroquinolones are important in human medicine for their ability to fight serious infections caused by food-borne bacteria. FDA approval came despite objections from experts with the Centers for Disease Control and Prevention (CDC) and evidence from Europe that animal use of fluoroquinolones would ultimately increase the number of people infected with bacteria resistant to the drug. In 2000, FDA concluded that the use of fluoroquinolones in poultry was "not shown to be safe" and sought to withdraw approval of this use. The contentious withdrawal process of Baytril, however, took five years during which resistance rates continued to rise and the ability to treat serious human health infections was further compromised.

Fourth-generation cephalosporins are critical for treating potentially fatal human infections, including those caused by *E. coli* and *salmonella*. Currently, no 4<sup>th</sup> generation cephalosporins are approved for use in food animals in the U.S. In Europe, where cefquinome has been approved for use in animal agriculture, scientists have noted an increase in resistance to cephalosporins among those bacteria.

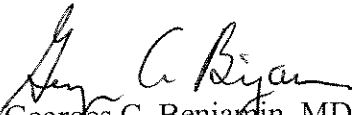
To protect the public's health by minimizing the eventual increase in human infections resistant to 4<sup>th</sup> generation cephalosporins, APHA urges the FDA to reject the application for the use of cefquinome in cattle. It is prudent to limit use of this important class of antibiotics *now* rather than after a problem arises.

If the FDA chooses not to accept the VMACs recommendations and instead approves 4<sup>th</sup> generation cephalosporins for use in cattle, APHA strongly urges that additional public health safeguards be put in place. These must include, at a minimum:

1. Enhanced national surveillance to include data on the quantity of 4<sup>th</sup> generation cephalosporins used in food animals.
2. Enactment of an extra-label prohibition to ensure that 4<sup>th</sup> generation cephalosporins are used only according to the label.

Thank you in advance for taking our concerns into consideration as you move forward with your decision on this important public health matter.

Sincerely,



Georges C. Benjamin, MD, FACP, FACEP (Emeritus)  
Executive Director