



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

7-1
June 12, 2003

TO: Dockets Management Branch
Food and Drug Administration

FROM: Commissioner of Food and Drugs

SUBJECT: SEPARATION OF FUNCTIONS: Enrofloxacin for Poultry
(Docket No. 00N-1571)


On October 31, 2000, the Food and Drug Administration (FDA) published a notice of opportunity for a hearing on the proposal to withdraw the approval of the new animal drug application for use of enrofloxacin in poultry. FDA published a revised notice on January 22, 2001. Bayer Corporation requested a hearing on this matter on November 29, 2000, and on February 20, 2002, FDA published a notice of hearing.

On April 16, 2003, an appeal was submitted to FDA under the Data Quality Act and implementing guidance concerning a risk assessment relating to the use of enrofloxacin in poultry. Under FDA's implementing guidance, routes for filing an appeal include the Office of the Commissioner. I am, therefore, designating the following persons in the Office of the Commissioner to participate in the review the data quality appeal:

Murray Lumpkin, M.D.
Susan Bond
Suzanne O'Shea

No other person in the Office of the Commissioner shall participate in the review of this data quality appeal unless designated in writing. The persons listed above may not advise the Commissioner or the Center for Veterinary Medicine in their functions relating to the withdrawal of the approval of the new animal drug application for use of enrofloxacin in poultry.

Although FDA's regulations do not require the Commissioner to file this separation of functions designation in the docket, I am doing so as a matter of policy.


Mark B. McClellan, M.D., Ph.D.

cc: HF-1
HFV-1
HFC-1
GCF-1

2000N-1571

SF 4