



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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.

I am designating the following persons as the principal advisors and staff to the Commissioner in this matter:

Lester Crawford, D.V.M., Ph.D.
Eric Flamm
Carl Cerniglia, Ph.D.
Rick Canady, Ph.D.
LaJuana Caldwell

As set out in 21 CFR 10.55(b)(ii), all members of FDA other than the representatives of the Center for Veterinary Medicine and those otherwise designated, are also available to advise the Commissioner and participate in the functions relating to the hearing and the final decision. 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

SF3