



1203 '04 APR -5 13:08

TO: Dockets Management Branch
Food and Drug Administration

FROM: Acting Commissioner of Food and Drugs

DATE: March 25, 2004

SUBJECT: SEPARATION OF FUNCTIONS: Oxytetracycline and Neomycin
Fixed-Combination Type A Medicated Articles (Docket No. 03N-0324)

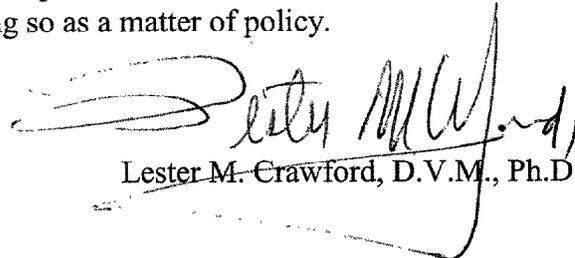
On August 8, 2003, the Center for Veterinary Medicine published a notice of opportunity for a hearing on the proposal to withdraw the approval of nine animal drug products and use combination, as part of its Drug Efficacy Study Implementation (DESI) program. On September 8, 2003, Pennfield Oil Co. requested a hearing on this matter for an oxytetracycline and neomycin fixed-combination Type A medicated article for use in animal feed, NADA 138-939.

Although FDA's regulations do not require separation of functions before the issuance of a notice of hearing on a proposed withdrawal of approval of a new animal drug application, it has been FDA's longstanding practice to apply separation of functions upon the agency's receipt of a request for a hearing. See, e.g., 46 FR 24694, 24696 (May 1, 1981).

I am designating the following persons as advisors to the Center for Veterinary Medicine in this matter:

Timothy Lynagh
Patrick McGarey

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.



Lester M. Crawford, D.V.M., Ph.D.

03N-0324

SF 2

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