Office of the Chief Counsel Food and Drug Administration 5600 Fishers Lane, GCF-1 Rockville, MD 20857

**MEMORANDUM** 

475 TO3 GCT 23 A9:57

Date

October 14, 2003

To:

Dockets Management Branch

Food and Drug Administration

From:

Daniel E. Troy

Chief Counsel

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). The Office of the Chief Counsel follows this practice.

I am designating the following attorneys as advisors to the Commissioner of Food and Drugs and to the Center for Veterinary Medicine.

Counsel for the Commissioner:

Daniel E. Troy Michael Landa Catherine Cook

Counsel for the Center for Veterinary Medicine:

Ann Wion
Joy Dawson
David Mednick

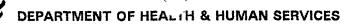
Undesignated attorneys may assist in advising the Center for Veterinary Medicine.

cc:

HF-1 HFV-1

03N-03240

SF1



Orrice of the General Counsel

Office of the Chief Counsel Food and Drug Administration 5600 Fishers Lane, GCF-1 Rockville, MD 20857

MEMORANDUM 7 4 7 5 '03 66T 23 A9:57

Date

October 14, 2003

To:

Dockets Management Branch Food and Drug Administration

From:

Daniel E. Troy

Chief Counsel

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). The Office of the Chief Counsel follows this practice.

I am designating the following attorneys as advisors to the Commissioner of Food and Drugs and to the Center for Veterinary Medicine.

Counsel for the Commissioner:

Daniel E. Troy Michael Landa Catherine Cook

Counsel for the Center for Veterinary Medicine:

Ann Wion
Joy Dawson
David Mednick

Undesignated attorneys may assist in advising the Center for Veterinary Medicine.

cc:

HF-1 HFV-1

03N-03240

SF1