



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

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

MEMORANDUM

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Date: October 14, 2003

To: Dockets Management Branch
Food and Drug Administration

From: Daniel E. Troy *DET*
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
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