



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

7475 '03 OCT 23 8:57

MEMORANDUM

**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  
HFV-1

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