



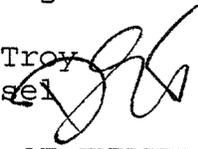
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Office of the Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, GCF-1  
Rockville, MD 20857

**MEMORANDUM**

**Date:** June 04, 2004

**To:** Staff Attorneys and  
Dockets Management Branch, Food and Drug Administration

**From:** Daniel E. Troy  
Chief Counsel 

**Subject:** SEPARATION OF FUNCTIONS: Delmont Laboratories, Inc.;  
Opportunity for a Hearing on a Proposal to Revoke U.S.  
License No. 299 (Docket No. 00N-1219)

On February 26, 2003, the Center for Biologics Evaluation and Research published a notice of opportunity for a hearing, pursuant to 21 C.F.R. Part 12 (Formal Evidentiary Public Hearing), on the proposal to revoke the biologics license issued to Delmont Laboratories, Inc. for Polyvalent Bacterial Antigens with "no U.S. Standard of Potency" (Staphage Lysate) (68 FR 8908). Delmont Laboratories, Inc. requested a hearing on March 27, 2003.

Pursuant to 21 C.F.R. §§ 12.50(d) and 10.55(c), the Office of the Chief Counsel is required to invoke separation of functions for Part 12 hearings.

I am designating the following attorneys as advisors to the Commissioner of Food and Drugs and to the Center for Biologics Evaluation and Research:

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