



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

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**MEMORANDUM**

**Date:** October 27, 2004

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

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

**Subject:** **REVISED - SEPARATION OF FUNCTIONS:** Baldev Raj Bhutani; Denial of Hearing;  
Final Debarment Order (Docket No. 2002N-0291)

On February 6, 2003, the Center for Drug Evaluation and Research (CDER) sent a certified letter to Baldev Raj Bhutani proposing to permanently debar Mr. Bhutani from providing services in any capacity to a person that has an approved or pending drug product application. The letter also provided Mr. Bhutani notice of an opportunity for a hearing on the proposal in accordance with Section 306 of the Act (21 U.S.C. 335a) and 21 CFR Part 12. In a letter dated January 30, 2003,<sup>1</sup> Mr. Bhutani requested a hearing on the proposed debarment.

Pursuant to 21 C.F.R. §§ 12.50 (d) and 10.55 (c), the Office of 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 Drug Evaluation and Research:

Counsel for the Commissioner:

- Daniel E. Troy
- Joy Dawson
- Donna Katz
- Mark Schwartz
- Nancy Stade
- Jennifer Gresock

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<sup>1</sup>Mr. Bhutani's response pre-dated his actual receipt of the certified letter. It appears that Mr. Bhutani was informed of FDA's initial attempt to serve him and he preemptively submitted his request for a hearing.

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Counsel for the Center for Drug Evaluation and Research:

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Undesignated attorneys may assist in advising the Center for Drug Evaluation and Research.

cc: HF-1      HFD-1      HFM-500  
HFC-1      HF-28      HFM-600  
HFC-230      HFM-1