



Office of the Chief Counsel
Food and Drug Administration
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Rockville, MD 20857

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MEMORANDUM

Date: October 12, 2004

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

From: Daniel E. Troy
Chief Counsel *DE*

Subject: SEPARATION OF FUNCTIONS: Thomas M. Rodgers, Jr.; Denial of
Hearing; Debarment Order (Docket No. 02N-0510)

On December 17, 2002, the Center for Biologics Evaluation and Research (CBER) sent a certified letter to Thomas M. Rodgers, Jr. proposing to debar Mr. Rodgers for 5 years from providing services in any capacity to a person that has an approved or pending drug product application, including but not limited to, a biologics license application. The letter also provided Mr. Rodgers 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 16, 2003, Mr. Rodgers, through his legal counsel, 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 Biologics Evaluation and Research:

Counsel for the Commissioner:

Daniel E. Troy
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Counsel for the Center for Biologics Evaluation and Research:

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Mark Raza
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Undesignated attorneys may assist in advising the Center for Biologics Evaluation and Research.

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