FOLEY
HOAG LLP
ATTORNEYS AT LAW

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Colin J. Zick
Boston Office
617) 832-1275
czick@foleyhoag.com

January 16, 2003

By FedEx

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 02N-0510 (Thomas M. Rodgers, Jr.)

Dear Sir or Madam:

Pursuant to 21 C.F.R. Part 12 and the December 17, 2002 letter from Kathryn C. Zoon, Ph.D, Director, Center for Biologics Evaluation and Research, I am writing on behalf of Thomas M. Rodgers, Jr. to request a hearing on the Food and Drug Administration's proposal to debar Mr. Rodgers in the proceeding under the docket number referenced above. Mr. Rodgers' objections to his debarment include the following:

(1) Mr. Rodgers' actions do not continue to undermine the process for the regulation of drugs by the Food and Drug Administration

The actions that underlay Mr. Rodgers' guilty plea occurred between August 1993 and April 1995, eight to ten years ago. Mr. Rodgers pled guilty and has served one year of probation for those offenses. His obligations and the legal consequences of those actions have now been concluded. As such, it is difficult to understand how Mr. Rodgers' conduct from 1993 through 1995 currently "undermines" the Food and Drug Administration's regulatory process, which finding is required pursuant to 21 U.S.C. § 335a(b)(2)(B) (Permitting debarment of "[a]ny individual whom the Secretary finds has been convicted of . . . a misdemeanor . . . for conduct relating to the development or approval of any drug product or otherwise relating to the regulation of drug products under this chapter . . . if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.") (Emphasis added.)

The courts have interpreted the purpose of debarment under 21 U.S.C. § 335a as the prevention of "present and future" problems, not punishment. Bae v. Shalala, 44 F.3d 489, 494 (7th Cir. 1995). The December 17, 2002 letter from Dr. Zoon does not speak to the present or future, but only the past, as it states that "FDA's process for the

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regulation of drug products was undermined" by Mr. Rodgers' actions, but does not find that his conduct has any *continuing* impact on FDA, let alone that his interaction with drug manufacturers "undermines" FDA at this time or will undermine FDA in the future. As such, the elements of the debarment statute have not been satisfied and Mr. Rodgers cannot be disbarred. Mr. Rodgers respectfully requests a hearing on this objection and all other objections herein.

(2) The descriptions of Mr. Rodgers' conduct in the December 17, 2002 are not found in the Information, despite the letter's statements to the contrary.

The description of Mr. Rodgers' conduct in the December 17, 2002 letter is not found in the Information, despite the letter's statements to that effect. In particular, the December 17, 2002 letter states, but the Information does not contain:

(a) a detailed description of LK-200 (e.g., that is was "a supernatant of white blood cell materials" or that it "meets the definition of a drug product"); or

(b) any claim that FDA was in fact "prevented from obtaining accurate and complete information necessary to regulate the drug process" by Mr. Rodgers.

As such, the findings in the December 17, 2002 letter are not supported by the sources cited in the "Conduct Related to Conviction." Such unsupported findings cannot justify debarment. Mr. Rodgers respectfully requests a hearing on this objection and all other objections herein.

In the event Mr. Rodgers is granted a hearing on these objections, he will provide additional evidence pursuant to the applicable regulations. If you have any questions regarding Mr. Rodgers' objections and hearing requests, please feel free to contact me.

Very truly yours,

Colin J. Zick

Enclosures (4 copies)

cc: Mr. Thomas M. Rodgers (by mail, w/o encl.)