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October 29, 2001

By FedEx

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

**NOTICE OF APPEARANCE AND REQUEST FOR HEARING
DOCKET NO. OON-1525**

Dear Sir or Madam:

Richard E. Humphreys, by counsel, hereby enters his Notice of Appearance and Request for Hearing in the above-referenced matter.

In a letter dated September 27, 2001, and received October 1, 2001, Janet M. Woodcock, M.D., Director of the Center for Drug Evaluation and Research, informed Mr. Humphreys that the Food and Drug Administration (FDA) proposed to issue an order permanently debarbing him from providing services in any capacity to a person that has an approved or pending drug product application based on his conviction of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act.

The September 27th notice offered Mr. Humphreys an opportunity for a hearing to show why he should not be debarred. The letter informed Mr. Humphreys that if he sought a hearing, he must file, on or before 30 days from the receipt of the September 27th letter, a written Notice of Appearance and Request for Hearing, and on or before 60 days from the receipt of the letter, the information on which he relies to justify a hearing.

This timely-filed letter serves as Mr. Humphreys' Notice of Appearance and Request for Hearing. Mr. Humphreys requests a hearing on the grounds that FDA's proposal to debar him was not initiated within five (5) years of his conviction of the underlying offense, as required by Section 306(1)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 335a(1)(2). Accordingly, FDA lacks statutory authority to debar him.

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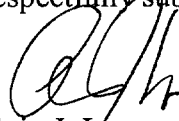
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In accordance with the provisions of 21 C.F.R. Part 12 and the September 27, 2001 letter, Mr. Humphreys will submit the data and information he relies upon to justify this hearing request on or before November 29, 2001.

Respectfully submitted,



Alvin J. Lorman

Attorney for Richard E. Humphreys

Filed in quadruplicate

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