

MINTZ LEVIN
COHN FERRIS
GLOVSKY AND
POPEO PC

Washington
Boston
New York
Reston
New Haven

701 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
202 434 7300
202 434 7400 fax
www.mintz.com

Alvin J. Lorman

Direct dial 202 434 7373
ajlorman@mintz.com

November 28, 2001

recd. 11/28/01

BY HAND

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

**INFORMATION RELIED UPON IN SUPPORT OF REQUEST FOR HEARING
DOCKET NO. 00N-1525**

Richard E. Humphreys, by counsel, hereby submits the data and information which he relies upon to justify the hearing which he requested on October 29, 2001, in connection with the agency's proposal to debar him.

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 debarring 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.

In accordance with the requirements of the September 27, 2001 letter, Mr. Humphreys timely filed a Notice of Appearance and Request for 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 21 U.S.C. § 335a(1)(2).

Section 306(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 335a(a)(2)(B), provides that FDA shall debar an individual from providing services in any capacity to a person that has an approved or pending drug product application if that individual "has been convicted of a felony under Federal law for conduct . . . otherwise relating to the regulation of any drug product under this Act"

00N-1525

SUP1

Dockets Management Branch (HFA-305)

November 28, 2001

Page 2

Section 306(l)(2), 21 U.S.C. § 335a(l)(2), provides that the mandatory debarment of subsection (a) "shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a)" Section 306(l)(1), 21 U.S.C. § 335a(l)(1), provides that:

For purposes of this section, a person is considered to have been convicted of a criminal offense -

. . .

(B) when a plea of guilty or nolo contendere by the person **has been accepted by a Federal or State court** (Emphasis added.)

The clear record in this case demonstrates that FDA initiated its action to debar Mr. Humphreys more than 5 years after the conviction which forms the basis of the agency's proposed action. Accordingly, FDA is without authority to debar Mr. Humphreys.

At a hearing, Mr. Humphreys will demonstrate that:

1. On July 15, 1996, he pled guilty in the United States District Court for the Eastern District of Virginia to one count of making false statements to an agency of the United States, a felony offense under 18 U.S.C. 1001. (FDA's letter of September 27, 2001 recites this fact, so it cannot be seriously in dispute.)

2. On July 15, 1996, the Court (Mehrig, J.) accepted Mr. Humphreys' plea of guilty and entered a judgment of conviction. A copy of the relevant pages of the docket sheet for the case, 3:96CR64-01, attached as Exhibit 1, shows that on this date the "Court accepted plea" and "Judgment of the Court: Deft Guilty as charged in Ct. 1 of the indictment." A transcript of the proceedings of July 15, 1996, attached as Exhibit 2, shows that Judge Mehrig, after explaining to Mr. Humphreys the consequences of his guilty plea, stated "I will accept the plea." Transcript of Hearing, July 15, 1996, at page 25, line 13. A little later, Judge Mehrig stated that, "The Court finds you guilty as charged in count one." Tr. at p. 27, line 1

3. Accordingly, the five year period during which FDA could initiate debarment proceedings against Mr. Humphreys pursuant to 21 U.S.C. § 335a(l)(2) ended on July 16, 2001.

4. FDA initiated debarment proceedings against Mr. Humphreys on October 1, 2001, when the agency's letter dated September 27, 2001 was received. It is obvious that FDA initiated this proceeding over two months after the expiration of the statutory five year period during which it was entitled to initiate a debarment proceeding.

5. FDA had ample time to move to debar Mr. Humphreys within the statutory five year period and failed to do so. Based upon the foregoing, FDA now lacks a factual or legal basis to debar Mr. Humphreys.

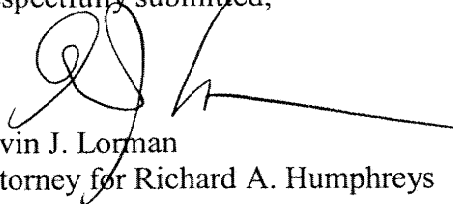
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.

Dockets Management Branch (HFA-305)

November 28, 2001

Page 3

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Alvin J. Lorman', with a long horizontal line extending to the right.

Alvin J. Lorman

Attorney for Richard A. Humphreys

Filed in Quadruplicate

WDC 225448v1