



December 17, 2002

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas R. Theodore
3 Robinwood Circle
Forestdale, MA 02644

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 02N-0511

Dear Mr. Theodore:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debaring you 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. FDA bases this proposal on its finding that you were convicted of nine felonies and three misdemeanors under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Conviction

On March 1, 2002, the United States District Court for the District of Massachusetts entered a judgment against you for nine Federal felony counts of mail fraud, 18 U.S.C. 1341. In addition, you were also found guilty of violating sections 301(p), 301(d), and 301(a) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 331(p), 331(d), and 331(a), for operating an unregistered drug facility, interstate distribution of an unapproved new drug, and interstate distribution of an adulterated drug. These were charged as Federal misdemeanors under section 303(a)(1) of the Act, 21 U.S.C. 333(a)(1).

According to the Indictment filed in the United States District Court for the District of Massachusetts, you, along with another individual, owned and operated Private Biologicals Corporation (PBC). PBC was in the business of producing an unapproved drug product named LK-200. The product was a supernatant of white blood cell material, and was distributed for use in treating cancer as well as other diseases. LK-200 meets the definition of a drug product within the meaning of section 201(dd) of the Act, 21 U.S.C. 321(dd). PBC used interstate carriers such as FedEx to ship the unapproved drug to recipients. PBC adulterated LK-200 in that the facilities

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and controls used in manufacture did not conform with current good manufacturing practice to assure that the product met the requirements of the Act as to safety and that LK-200 had the identity, strength, and quality it was represented to possess. In addition, you never registered the PBC manufacturing facility located in Woburn, Massachusetts. Moreover, you never sought approval to distribute the LK-200 product, and did not request an investigational exemption to distribute the product.

FDA's Finding

We find that you have been convicted of nine felonies under Federal law, 18 U.S.C. 1341, for conduct relating to the regulation of a drug product. Under sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the Act, 21 U.S.C. §§ 335a(a)(2)(B) and 335a(c)(2)(A)(ii), debarment is mandatory and permanent for an individual found convicted of a felony under Federal law for conduct relating to the regulation of any drug product.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(B) of the Act, 21 U.S.C. 335a(a)(2)(B), permanently debarring you 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.

In accordance with section 306 of the Act and Title 21, Code of Federal Regulations (21 CFR) Part 12, by this letter you are given notice of an opportunity for a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file on or before 30 days from the date of receipt of this letter, a written request for hearing and objections. The regulations regarding a request for hearing are set forth at 21 CFR Part 12.

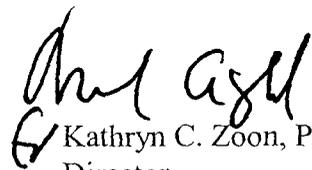
Your failure to file a timely written request for hearing would constitute a waiver of objections concerning your debarment. If you do not request a hearing in the manner prescribed by the regulations, the agency will deny your request for a hearing and issue a final order. A request for hearing based on mere allegations, denials, or general descriptions of positions and contentions will not be granted. Nor will a hearing be granted on issues of policy or law. To obtain a hearing, you must present specific facts showing that there is a genuine and substantial issue of fact.

The facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted of felonies under Federal law for conduct relating to the regulation of a drug product.

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Your request for a hearing, including any material submitted in support of any objection, must be identified with Docket No. 02N-0511, and sent to: Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1061, 5630 Fishers Lane, Rockville, Maryland, 20852. Please file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR Part 10.20(j). Publicly available submissions may be examined in the Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

Sincerely,



Kathryn C. Zoon, Ph.D.
Director

Center for Biologics Evaluation and Research

cc: Thomas R. Theodore
c/o FCI Allenwood (Low)
P.O. Box 1500
White Deer, Pennsylvania 17887

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- Print your name and address on the reverse so that we can return the card to you.
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1. Article Addressed to:

Mr. Thomas R. Theodore
3 Robinwood Circle
Forestdale, MA 02644

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