DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 8 2003

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Ray Courtney
FCI Greenville
P.O. Box 4000
100 U.S. Route 40
Greenville, Illinois 62246

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 03N-0102

Dear Mr. Courtney:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted of a felony under Federal law for conduct otherwise relating to the regulation of any 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 February 26, 2002, you entered into an agreement pleading guilty to 8 counts of tampering with consumer products in violation of 18 U.S.C. sections 1365(a) and (a)(3), and 6 counts each of misbranding and adulterating drugs in violation of sections 301(k) and 303 (a)(2) of the Act (21 U.S.C. 331(k) and 333(a)(2)). On December 5, 2002, the United States District Court for the Western District of Missouri sentenced you to the maximum 30 years in prison and required you to pay a fine of $25,000 and $10.4 million in restitution for diluting drugs you dispensed to your pharmacy customers. Such drugs included the chemotherapy medications Gemzar (gemcitabine) and Taxol (paclitaxel). The underlying facts supporting this felony conviction are as follows:

At the time of your criminal actions, you were a pharmacist and owner of Courtney Pharmacy, Inc., d/b/a Research Medical Tower Pharmacy, a company that operated two pharmacies: Research Medical Tower Pharmacy in Kansas City, Missouri, and Courtney Pharmacy in Overland Park, Kansas. Among other things, you were responsible for mixing, preparing, labeling, and distributing intravenous drug mixtures.

In July 2001, a Kansas City oncologist, Dr. Verda Hunter, notified FBI and FDA agents that a salesman from the drug manufacturer Eli Lilly and Co. had told her that you were dispensing more of the drug Gemzar than you were purchasing. The agents then set up an investigation which revealed that certain medications you dispensed were far less potent than the medications ordered by Dr. Hunter. One drug sample contained less than 1 percent of the prescribed amount.

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This investigation resulted in the filing of a complaint on August 14, 2001, charging you with adulteration and misbranding. At this time, you voluntarily presented yourself to law enforcement agents for the purpose of being interviewed. During this interview, you admitted to the allegations in the complaint and you also admitted to diluting numerous other drugs used in chemotherapy treatment. You later told authorities that you had routinely purchased pharmaceutical and controlled substances on the gray market, including purchases of Gemzar and Taxol.

It was eventually determined that more than 4,000 patients may have had their prescriptions diluted by you over a 10-year period. The investigation and admissions culminated in your guilty plea to all 20 counts of the indictment.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. 335a(a)(2)(B)) requires mandatory debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the Act. Your felony conviction under Federal law (i.e., sections 301(k) and 303 (a)(2) of the Act) for the misbranding and adulteration of prescription drug products constitutes conduct related to the regulation of drug products under the Act. Your illegal acts leading to this conviction are a direct violation of the primary legislation regulating drugs.

Under section 306(l)(2) of the Act (21 U.S.C. 335a(1)(2)), mandatory debarment applies when an individual was convicted up to 5 years prior to this notice. Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

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 permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity for a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing, and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of

appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning your debarment. If you do not request a hearing in the manner prescribed by the regulations, the Agency will not hold a hearing and will issue the debarment order as proposed in this letter.

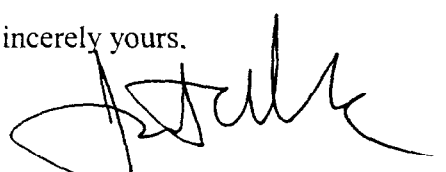
A request for hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in your request for hearing that there is no genuine and substantial issue of fact which precludes the order of debarment, the Commissioner of Food and Drugs will enter summary judgment against you, making findings and conclusions, and denying a hearing.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates your debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 03N-0102 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. You must file four copies of all submissions under this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.34).

Sincerely yours,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research