DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MAY 14 2009

Paul H. Kornak
07010-067
FCI Schuylkill
Federal Correctional Institution
P.O. Box 759
Minersville, PA 17954

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2007-N-0501[1]

Dear Mr. Kornak:

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 three felonies under federal law for conduct relating to the development or approval of a drug product and otherwise 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 to request a hearing on the proposal.

Conduct Related to Conviction

On January 18, 2005, the United States District Court for the Northern District of New York accepted your plea of guilty (plea agreement) and entered judgment against you for one count of making and using a materially false statement in violation of 18 U.S.C. § 1001(a)(3), one count of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346, and one count of criminally negligent homicide in violation of 18 U.S.C. § 13 and New York Penal Law § 125.10. The underlying facts supporting these felony convictions are as follows:

Beginning in October 2000, you were employed by the Department of Veterans Affairs as a program specialist at the Stratton Veterans Affairs Medical Center (Stratton) in Albany, New York. At Stratton, you were the site coordinator for several pharmaceutical study protocols,

[1] Legacy Docket No. 2007N-0452.

specifically the FeAST,[2] Tax 325,[3] Tax 327,[4] and DFMO[5] studies. These clinical studies were conducted to evaluate the safety and efficacy of drug products. Data from such studies are considered by FDA in determining whether to grant or withhold approval of a drug product. Your duties included coordinating pharmaceutical research protocols, and you were responsible for adhering to system standards and complying with research requirements.

From about May 14, 1999,[6] through July 10, 2002, in connection with conducting and coordinating clinical studies at Stratton, including the FeAST, Tax 325, Tax 327, and DFMO studies, you participated in a scheme to defraud the sponsors of these studies, by repeatedly submitting false documentation and enrolling and causing to be enrolled persons as study subjects who did not qualify under particular study protocols. In addition to other specific acts cited in the plea agreement, you admitted to:

- Submitting a case report form with regard to a study subject knowing the document contained materially false laboratory entries and altered information from a radiology display report, which were critical factors in determining whether the individual was eligible to participate in the Tax 325 study (violation of 18 U.S.C. § 1001(a)(3)).

- Knowingly and willfully misrepresenting the results of a blood chemistry analysis related to the participation of a Tax 325 study subject who would not otherwise have met the criteria for that study. The subject was administered the chemotherapeutic drugs docetaxel, cisplatin, and 5-FU in connection with Tax 325 and died as a result thereof. Your failure to perceive a substantial and unjustifiable risk that death would occur when you knowingly and willfully made and used such false documents constituted a gross deviation from the standard of care that a reasonable person would observe in the situation (violation of 18 U.S.C. §§ 1001(a)(3) and 13, and New York Penal Law § 125.10)).

- Knowing and willfully using interstate mail for the purpose of executing the aforesaid scheme and artifice to defraud, deprive, and obtain money and property (violation of 18 U.S.C. §§ 1341 and 1346).

On November 21, 2005, as a result of your guilty pleas, you were sentenced to 60 months in prison on Count 1 (making and using false statements), 71 months in prison on Count 15 (mail fraud) and 48 months in prison on Count 48 (criminally negligent homicide), all terms imposed concurrently. You were also ordered to make restitution to the sponsors of the clinical studies: to Aventis Pharmaceuticals in the amount of $488,907.58; to ILEX Oncology, Inc., in the amount of $14,017.47; and to the U.S. Department of the Treasury for losses incurred to the U.S. Department of Veterans Affairs in the amount of $135,850.

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[2] VA Cooperative Study #410, the Iron (Fe) and Atherosclerosis (AST) Study known as "FeAST," was a clinical trial that tested a new procedure for controlling atherosclerosis.
[3] This was a randomized study of patients with metastatic or locally recurrent cancer previously untreated with chemotherapy for advanced disease.
[4] This was a randomized trial for patients with metastatic hormone refractory prostate cancer.
[5] This study compared the use of difluoromethylornithine (DFMO) to the use of placebo in treating low- grade superficial bladder cancer.
[6] At that time, until October 2000, you were employed by Albany Research Institute, Inc., at Stratton.

FDA's Finding

Section 306(a)(2)(A) of the Act (21 U.S.C. § 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Because the FeAST, Tax 325, Tax 327, and DFMO studies were conducted to evaluate the safety and efficacy of drug products, and FDA determines whether to grant or withhold approval of a drug product based, in part, on the data from such studies, FDA finds that the actions described in the plea agreement relate to both the development and approval of drug products.

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) requires 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. FDA finds that the felonies referred to in the plea agreement were also for conduct otherwise relating to the regulation of a drug product under the Act because it related to your conduct of drug studies regulated by FDA.

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)(A) and (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 to request a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file the following: (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 your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, the Agency will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a 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. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to

justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

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. FDA-2007-N-0501 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You must 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 § 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement, Office of Regulatory Affairs (FDA Staff Manual Guide 1410.35).

Sincerely,

Alyson L. Saben
Acting Director
Office of Enforcement
Office of Regulatory Affairs