DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Wayne E. Spencer
(b) (6)

6-20-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2012-N-0355

Dear Dr. Spencer:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) 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 one count of failing to prepare and maintain records required under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the Act, 21 U.S.C. § 355(i)) with intent to defraud and mislead, in violation of section 301(e) of the Act (21 U.S.C. § 331(e)), which, according to section 303(a)(2) of the Act (21 U.S.C. § 333(a)(2)), constitutes a felony under Federal law. The conduct that served as the basis for your conviction relates to the development or approval, including the process for development or approval, of a drug product under the Act.

This letter also offers you an opportunity to request a hearing on the proposal.

Conduct Related to Conviction

On October 19, 2011, you entered a guilty plea to one felony count of conspiracy to defraud, in violation of 18 U.S.C. §§ 371 and 2, and another felony count of failing to prepare and maintain records required under section 505(i) of the Act, with the intent to defraud and mislead, in violation of sections 301(e) and 303(a)(2) of the Act (21 U.S.C. §§ 331(e), 333(a)(2), and 18 U.S.C. § 2. Judgment was entered against you in the United States District Court for the District of Kansas on March 7, 2012. According to the Indictment filed on June 1, 2011, the underlying facts supporting this conviction are as follows.

You were a licensed medical doctor practicing medicine in the District of Kansas, and you were the Principle Investigator for a Schering/Plough clinical study.

Schering/Plough was a pharmaceutical company engaged in developing and marketing pharmaceutical products, including a sublingual tablet developed for the treatment of allergies. Under the Act and its implementing regulations, Schering/Plough had to apply to FDA for approval to market their sublingual tablet. Schering/Plough was required to demonstrate, through clinical investigations, the safety and effectiveness of the sublingual tablet before FDA would approve it for human use or consumption. As part of the process for the development and approval of drug products, FDA examines the results, design, and conduct of the clinical studies in deciding whether any new drug should be approved for marketing.

In or about July 2009, Schering/Plough chose Lee Research Institute, your employer, to perform a clinical study known as "A 28-Day Study Evaluating the Safety of Ragweed Sublingual Tablet in Adult Subjects 50 years of age and Older with Ragweed-Induced Rhino conjunctivitis" (the clinical study). You were the principal investigator for the clinical study at Lee Research Institute.

Before beginning the clinical study, FDA required Schering/Plough to provide the Agency with a study protocol. The study protocol contained information about how the clinical study would be conducted, where studies would be done and by whom, how the drug's safety would be evaluated, and what findings would require the study to be changed or halted.

All participating clinical investigators, which included Ms. Lisa Jean Sharp, the Director of Clinical Trials for Lee Research Institute and the Lead Clinical Research Coordinator for the clinical study, signed FDA Forms 1572, committing to conduct the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations.

According to the study protocol, each subject enrolled had to be 50 years of age and older. Additionally, the study protocol excluded subjects who were a member or a family member of the personnel of the investigational or sponsor staff directly involved with the clinical trial.

Beginning in or about January 2010, and continuing through in or about May 2010, in the district of Kansas, you and Ms. Sharp, with the intent to defraud and mislead, failed to prepare and maintain records required under section 505(i) of the Act (21 U.S.C. § 355(i)) and 21 C.F.R. § 312.62(b). The records you were required to maintain included adequate and accurate case histories on each individual who was administered Schering/Plough's investigational drug. You falsified the birth dates of two participants such that they appeared to be older than 50 years of age; falsely indicated that physical examinations had been performed, when they had not been performed; and indicated on required forms that two participants met the inclusion criteria and had no reasons for exclusion, when you knew that the participants did not meet the inclusion criteria of age and should have been excluded as employees of the research facility conducting the clinical study. This was in violation of 18 U.S.C. § 371, as well as sections 301(e) and 303(a)(2) of the Act (21, U.S.C. §§ 331(e), 333(a)(2)).

FDA's Findings

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 a drug product under the Act. FDA finds that your felony conviction for failure to prepare and

maintain records required pursuant to sections 301(e) and 505(i) of the Act (21 U.S.C. §§ 331(e), 355(i)) is sufficient to support debarment for conduct relating to the development or approval of a drug product under the Act.[1]

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) of the Act (21 U.S.C. § 335a(a)(2)(A)) 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 (21 U.S.C. § 335a) and 21 C.F.R. 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 under section 306(a)(2)(A) of the Act (21 U.S.C. § 335a(a)(2)(A)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2012-N-0355 and sent to the Division of

[1] In this Notice, we do not address whether your felony conviction would provide an alternate ground sufficient to support your debarment.

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,

Armando Zamora
Acting Director,
Office of Enforcement
Office of Regulatory Affairs

cc:

HF-22/Matthew Warren
HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Ilisa Berstein
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/Keith Webber
HFC-2/ Michael Verdi

HFD-45/Ball, Leslie
HFD-45/Constance Cullity
HFD-45/Susan K. Cummins
HFD-45/Thomas Moreno
HFD-45/Karena Cooper
HFD-45/David Burrow
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF