DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Maria Carmen Palazzo/29650-034
FCI Coleman Medium
Federal Correctional Institution
P.O. Box 1032
Coleman, Fl 33521

01-11-2011

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2010-N-0450

Dear Dr. Palazzo:

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 felonies under Federal law for (1) conduct relating to the development or approval, including the process for development or approval, of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act) and (2) otherwise relating to the regulation of any drug product under the Act. This letter also offers you an opportunity to request a hearing on the proposal and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On August 19, 2010, the United States District Court for the Eastern District of Louisiana accepted your plea of guilty, and entered judgment against you for fifteen counts of failure to prepare and maintain records with intent to defraud or mislead in violation of 21 U.S.C. §§ 331(e), 333(a)(2), and 18 U.S.C. § 2; The underlying facts supporting the felony convictions relevant to this Proposal to Debar are as follows.

You were a duly licensed Medical Doctor specializing in psychiatry, with offices located in New Orleans, Louisiana. SmithKline Beecham, Corporation, d/b/a GlaxoSmithKline (SKB) was a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products including Paroxetine, also known as "Paxil," developed by SKB for the treatment of Obsessive Compulsive Disorder.

Under the Act and its implementing regulations, SKB had to apply to the FDA, for approval to market Paxil. SKB was required to demonstrate, through clinical investigations in which Paxil was given to human subjects, the safety and effectiveness of the drug in order to receive approval from the FDA. The FDA examined the results, design, and conduct of the clinical studies in deciding whether Paxil would be approved for marketing. Before beginning the Paxil clinical study, the FDA required SKB to provide the FDA with a detailed investigational plan which included information about the clinical study, how the study would be conducted, where the 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 terminated. The FDA needed truthful and adequate information regarding the SKB study in order for the Agency to effectively evaluate the safety and performance of Paxil.

SKB hired physicians, known as clinical investigators, to carry out the clinical studies of the drug on human subjects. On October 31, 2000 and again on February 9, 2001, SKB hired you to be a clinical investigator for the Paxil study. As a participating investigator you signed, on multiple occasions, a FDA Form 1572 committing you to conduct the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations. You agreed to conduct the study in strict compliance with the criteria set forth in the study protocol and to personally review all Case Report Forms which contained information regarding each study subject. In return SKB agreed to pay you for each subject who completed the study.

FDA regulations required that, as a clinical investigator on a drug study, you prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each study subject and provide that information to the drug sponsor. From on or about October 23, 2000, through May 24, 2001, you, with intent to defraud and mislead, failed to prepare and maintain records required under 21 U.S.C. § 355(i), and 21 C.F.R. § 312.62(b), all in violation of 21 U.S.C. §§ 331(e), 333(a)(2) and 18 U.S.C. § 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 any one of your fifteen felony convictions for failure to prepare and maintain records on the Paxil study subjects as required by the Act is sufficient to support debarment for conduct relating to the development or approval of a drug product under the Act. Your felony convictions were also for conduct otherwise relating to the regulation of a drug product under the Act because they related to your conduct of a clinical investigation regulated by FDA (21 U.S.C. § 335a(a)(2)(B)).

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 (21 U.S.C. § 335a(a)(2)(A)-(B)) 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 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) and (B) of the Act (21 U.S.C. § 335a(a)(2)(A)-(B)) 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-2010-N-0450 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.

You also may notify the Secretary that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to the Secretary in accordance with section 306(c)(2)(B) (21 U.S.C. § 335a(c)(2)(B)).

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,

Howard R. Sklamberg, Esq.
Director
Office of Enforcement
Office of Regulatory Affairs

cc:
HF-3/Daniel J. Davidson

HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Deborah Autor
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/ Keith Webber
HFC-2/ Michael Verdi

HFD-45/Ball, Leslie
HFD-45/Constance Lewin
HFD-45/Sherbet Samuels
HFV-200/Daniel G. McChesney

HFA-305 (Docket No. FDA-2010-N-0450)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF