DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MAY 14 2009

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2008-N-0582

Dear Dr. Hendrick:

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 relating to the development or approval, including the process for development or approval, of a drug product and that otherwise related 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 this proposal.

Conduct Related to Conviction

On September 11, 2007, the United States District Court for the Eastern District of Michigan accepted your guilty plea and entered judgment against you for one count of mail fraud, under 18 U.S.C. § 1341. You were sentenced to nine (9) months in prison for this offense. On September 18, 2008, your sentence was amended to weekend incarceration for seven (7) months, followed by nine (9) months of electronic monitoring and three (3) years of probation. The following details the underlying facts supporting your felony conviction:

Between 2000 and 2003, you were a licensed physician practicing medicine in the State of Michigan. You agreed to participate in the clinical research trial for Augmentin XR, including its use in the treatment of adults with Acute Bacterial Sinusitis (ABS). As part of your participation in the clinical study, you agreed to conduct the study in conformity with the protocol established by GlaxoSmithKline and comply with FDA regulations. You also agreed to take X-rays, before and after treatment, of persons you diagnosed with ABS, and to have an independent radiologist analyze these and issue reports regarding the X-rays.

As part of your plea agreement, you admitted that instead of having an independent radiologist review the X-rays and issue reports, you allowed certain X-rays to be sent in batch form, which was a direct violation of the protocol. Further, you did not verify the purported signatures of the independent radiologist reports and, instead, failed to disclose to GlaxoSmithKline and/or the FDA that the signatures were unverified and possibly forged, with the intent to create a false impression of a state of facts. You were paid by GlaxoSmithKline approximately $116,800 in X-ray fees for your participation in the clinical research trial. In so doing you did cause on or about March 4, 2003, a check to be mailed to you through the Postal Service at the direction of GlaxoSmithKline as partial

payment for your participation in the clinical trial for the purpose of executing the scheme to defraud.

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. FDA finds that you were convicted of a felony under federal law for conduct relating to the development or approval of Augmentin XR for the treatment of acute bacterial sinusitis (ABS).

You pled guilty to one count of mail fraud, in violation of 18 U.S.C. § 1341. Because the clinical studies sponsored by GlaxoSmithKline were conducted to evaluate the safety and efficacy of a drug product, and FDA determines whether to grant or withhold approval of a drug product based, in part, on the data from such a study, the actions for which you were convicted related 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. Your felony conviction under 18 U.S.C. § 1341 was also for conduct otherwise relating to the regulation of a drug product under the Act because it related to your conduct of a clinical investigation regulated by the Agency. (See 21 CFR part 312). 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-2008-N-0582 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 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 within the Food and Drug Administration.

Sincerely,

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