DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2008-N-0137

Dear Dr. Sawaya:

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: (1) relating to the development or approval, including the process for development or approval, of any drug product; and (2) 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 to request a hearing on this proposal.

Conduct Related to Conviction

On December 11, 2003, the United States District Court for the Middle District of Florida accepted your plea of guilty and adjudged you guilty of one count of making a false statement to a federal agency, a federal felony offense under 18 U.S.C. 1001. On January 22, 2004, the court sentenced you to 24 months of probation for this offense. Pursuant to your guilty plea, you admitted to the following facts:

You have both M.D. and Ph. D. degrees, and your work was limited to conducting research in the field of steroid biochemistry as it relates to skin and hair diseases. Because of your research in the area of alopecia (hair loss), various pharmaceutical companies requested that you conduct clinical trials of new drugs associated with hair growth and hair loss.[1]

In that capacity, you knowingly and willfully made and used a false document knowing the same to contain a materially false, fictitious, and fraudulent statement or entry in a

[1] More information about these investigations is set forth in a separate agreement with FDA ("Agreement with Respect to the Use of Investigational Products"), which you signed on September 8, 2003, and the terms and provisions of which you agreed to be fully incorporated into the Plea Agreement dated September 8, 2003 (Plea Agreement, pp. 7-8).

matter within the jurisdiction of FDA. Specifically, you served as clinical investigator for a clinical trial of the drug eflornithine hydrochloride (HCl) for the treatment of pseudofolliculitis barbae in males (ingrown facial hair) sponsored by Bristol-Myers Squibb Company (BMS). At some point in the beginning of the clinical trial process, BMS requested that you provide your medical license to include in their application to FDA.

Although you received M.D. and Ph.D. degrees, you have never been licensed as a physician in the United States. You created a medical license by obtaining a copy of a colleague's Florida medical license and altering that license using a photocopy machine to reflect that the license was issued in your name. In November 1998, you submitted to BMS the false and fraudulent Florida medical license. BMS then submitted that license to FDA in February 1999 as part of the drug approval process of eflornithine HCl to treat ingrown facial hair. When the false license was due to expire, you once again created a false and fraudulent medical license with a different expiration date and submitted that license to BMS.

Before approving a new drug for marketing, FDA generally requires that drug manufacturers (sponsors) demonstrate, through clinical trials, the drug's safety and effectiveness. When conducting such studies, sponsors often retain the services of clinical investigators. When selecting clinical investigators, sponsors rely on the investigators' credentials, including their licensing. When sponsors submit applications to FDA to initiate clinical trials and to seek approval to market drug products, they must, among other things, provide information on the qualifications of each clinical investigator. When evaluating such applications and the results of such studies, FDA reviews and relies upon the credentials of the clinical investigators, including their licensing.

You have admitted to causing BMS to submit a false and fraudulent medical license to FDA, that the medical license was material to the FDA's review of an investigational drug, and that you acted willfully and with intent 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 eflornithine HCL for the treatment of pseudofolliculitis barbae.

You pleaded guilty to one count of making a false statement to a Federal agency by providing a false and fraudulent medical license to BMS that was submitted to FDA, in violation of 18 U.S.C. 1001. Because the clinical studies sponsored by BMS 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 qualifications of the clinical investigators who conduct such studies, the actions for which you were convicted related to both the development and approval of a drug product.

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. 1001 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 sections 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. Information gathered indicates that you are also known as "Marty Sawaya," and FDA proposes to list this name in the debarment order as a name by which you are also known.

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.[2]

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.

[2] In the plea agreement, you agreed that you are "permanently foreclosed from acting as a clinical investigator or in any other capacity related to the investigational study of drugs that will . . . be submitted to . . . [FDA]" and that you will not be involved in any way with the receipt of investigational drugs, animal drugs, biologics, devices, or food additives intended or required for submission to the FDA (pp. 7-8). However, the plea agreement does not indicate that you agreed to the full range of permanent debarment, i.e., that you may not provide services in any capacity to a person that has an approved or pending drug product application, as required by section 306(a)(2) of the Act (21 U.S.C. 335a(a)(2)), not just in connection with investigations. Accordingly, we are sending you this notice of opportunity for a hearing on the proposal to debar.

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-0137 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 Acting Associate Commissioner for Regulatory Affairs of the Food and Drug Administration.

Sincerely,

Michael A. Chappell
Acting Associate Commissioner
for Regulatory Affairs