respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: June 4, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–13841 Filed 6–11–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0137]

Mary E. Sawaya a.k.a. Marty Sawaya; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Dr. Mary E. Sawaya a.k.a. Marty Sawaya (Dr. Sawaya) from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Sawaya was 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 conduct otherwise relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Dr. Sawaya failed to request a hearing. Dr. Sawaya's failure to request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective June 12, 2009.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Hummel, Sr., Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6845.

SUPPLEMENTARY INFORMATION:

I. Background

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. Section 306(a)(2)(B) of the act 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.

On December 11, 2003, the U.S. District Court for the Middle District of Florida accepted Dr. Mary E. Sawaya's plea of guilty and convicted her of one count of making a false statement to a Federal agency, a Federal felony offense under 18 U.S.C. 1001. This offense was committed when Dr. Sawaya created a medical license by obtaining a copy of a colleague's Florida medical license, altered that license using a photocopy machine to reflect that the license was issued in her name, and submitted the false and fraudulent Florida medical license to the sponsor of a clinical trial, for which she was a clinical investigator. The sponsor submitted that license to FDA as part of the drug approval process. When the false license was due to expire, Dr. Sawaya once again created a false and fraudulent medical license with a different expiration date and submitted that license to the clinical trial sponsor.

As a result of this conviction, FDA sent Dr. Sawaya by certified mail on November 26, 2008, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Dr. Sawaya was 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 conduct otherwise relating to the regulation of a drug product under the act. The proposal also offered Dr. Sawaya an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Sawaya did not request a hearing and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) and (a)(2)(B) of the act, and under authority delegated to her, finds that Dr. Sawaya 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 and conduct otherwise relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Dr. Sawaya is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**). (See sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd)).) Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Sawaya, in any capacity, during Dr. Sawaya's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Sawaya , during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Sawaya during her period of debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Sawaya for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2008–N–0137 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. 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.

Dated: June 1, 2009.

Alyson L. Saben,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

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