

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On June 18, 2008, Dr. Ruetschi pleaded guilty to a misdemeanor offense of receipt and delivery of a misbranded drug in interstate commerce in violation of 21 U.S.C. 331(c), 333(a)(1), and 352(f). On July 2, 2008, the U.S. District Court for the Central District of California entered judgment against Dr. Ruetschi for receipt in interstate commerce of misbranded drug and delivery thereof.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Dr. Ruetschi was a licensed medical doctor in the State of California and maintained an office in Palm Desert, CA. Beginning on or about January 20, 2004, and continuing until on or about October 20, 2004, Dr. Ruetschi began ordering from Toxin International, Inc., (TRI) an unapproved drug product represented to be a Botulinum Toxin Type A product (TRI-toxin). Specifically, Dr. Ruetschi placed 11 orders for a total of 11 vials of TRI-toxin, which was shipped in interstate commerce from Tucson, AZ to her office in Palm Desert, CA. Dr. Ruetschi subsequently administered the TRI-toxin to her patients for the treatment of facial wrinkles. The TRI-toxin bore warnings that it was not for human use and did not bear any directions for human use, and was misbranded under 21 U.S.C. 352(f) in that it lacked adequate directions for use.

As a result of her convictions, on January 5, 2011, FDA sent Dr. Ruetschi a notice by certified mail proposing to debar her for 5 years 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(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)), that Dr. Ruetschi was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Ruetschi 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. Ruetschi failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Maja S. Ruetschi has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Dr. Ruetschi is debarred for 5 years 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 FD&C 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), (c)(2)(A)(iii), and 201(dd) of the FD&C 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. Ruetschi, in any capacity during Dr. Ruetschi's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Ruetschi provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with

the assistance of Dr. Ruetschi during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Ruetschi for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2010-N-0474 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: March 23, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011-7782 Filed 4-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0476]

Marilyn A. Mehlmauer: 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 FD&C Act) debarring Marilyn Mehlmauer, MD for 4 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Dr. Mehlmauer was convicted of a misdemeanor under Federal Law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. Dr. Mehlmauer was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Mehlmauer failed to respond. Dr. Mehlmauer's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective April 4, 2011.

ADDRESSES: Submit applications for 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:

Kenny Shade, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On November 13, 2007, Dr. Mehlmauer pleaded guilty to a misdemeanor offense of Receipt in Interstate Commerce of Misbranded Drug and Delivery thereof in violation of 21 U.S.C. 331(c), 333(a)(1), and 352(f). On November 13, 2007 the U.S. District Court, for the Central District of California entered judgment against Dr. Mehlmauer for misdemeanor misbranding.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Dr. Mehlmauer was a physician with an office located in Pasadena, CA. In August 2003, Dr. Mehlmauer began ordering an unapproved drug product represented to be a Botulinum Toxin Type A drug product (TRI-toxin) manufactured by Toxin Research International, Inc. (TRI), located in Tucson, AZ. From on or about August 27, 2003, and continuing to on or about November 22, 2004, Dr. Mehlmauer placed 12 orders for a total of 26 vials of TRI-toxin, which she had shipped to her office. The TRI-toxin did not come with labeling or directions on how to dilute the product for injection, and therefore was misbranded under 21 U.S.C. 352(f) in that it lacked adequate directions for use. The TRI-toxin label stated "for research purposes only" and "not for human use." Dr. Mehlmauer admitted to injecting the unapproved TRI-toxin into patients and on some occasions to representing to patients that the TRI-toxin was BOTOX®/BOTOX® Cosmetic, at that time the only approved Botulinum Toxin Type A drug. Dr. Mehlmauer delivered and proffered for delivery the unapproved, misbranded TRI-toxin when she

ordered, received, and administered it to other persons, all in violation of 21 U.S.C. 331(c), 333(a)(1), and 352(f).

As a result of her convictions, on January 19, 2011, FDA sent Dr. Mehlmauer a notice by certified mail proposing to debar her for 4 years 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(b)(2)(B)(i)(I) of the FD&C Act, that Dr. Mehlmauer was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Mehlmauer 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. Mehlmauer failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Marilyn Mehlmauer has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Dr. Mehlmauer is debarred for 4 years 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 FD&C 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 section 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C 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. Mehlmauer, in any capacity during Dr. Mehlmauer's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr.

Mehlmauer provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Mehlmauer during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Mehlmauer for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2010-N-0476 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: March 23, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0464] (Formerly Docket No. 2006D-0331)

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception From Informed Consent for Emergency Research; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent for Emergency Research." This guidance is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors in the development, conduct, and oversight of research involving FDA-regulated products (e.g., drugs, biological products, devices) in emergency settings when an exception from the informed consent requirements is requested under the Code of Federal Regulations (CFR). FDA determined that