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.

[FR Doc. 2011–7783 Filed 4–1–11; 8:45 am]

BILLING CODE 4160–01–P

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

guidance is needed in interpreting and complying with these regulations, particularly in the areas of planning and conducting community consultation and public disclosure activities, and the establishment of informed consent procedures to be used when feasible. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 2006.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400), or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sara Goldkind, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

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 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 title 21 of the CFR (21 CFR 50.24). The exception applies to investigations to determine the safety and/or effectiveness of FDA-regulated products used in emergency settings (emergency research). These investigations involve human subjects who have a life-threatening medical condition (for which available treatments are unproven or unsatisfactory), and who, because of their condition (*e.g.,* traumatic brain injury), cannot give informed consent. The research involves an investigational product that, to be effective, must be administered before informed consent from the subjects' legally authorized representatives can be obtained.

In the **Federal Register** of August 29, 2006 (71 FR 51198), FDA announced the availability of the draft guidance of the same title, dated July 2006. The same **Federal Register** (71 FR 51143) announced a public hearing, held on October 11, 2006, on emergency research conducted without informed consent under FDA's emergency research regulations.

FDA received numerous comments on the draft guidance. All comments received during the comment period, questions received by Agency staff related to implementation of the regulations, and information presented at the public hearing have been carefully reviewed and, where appropriate, incorporated into the guidance. A summary of changes includes the following: (1) Additional discussion of the goals and purpose of community consultation and public disclosure, information that should be included, and how community consultation and public disclosure activities may be implemented; (2) clarification of "unproven" and "unsatisfactory" with respect to available therapy; and (3) discussion of trial design issues (*e.g.*, study endpoints, therapeutic window. This guidance incorporates comments received on earlier drafts of the guidance document, questions received by Agency staff related to implementation of the regulations, and information presented at the October 11, 2006, public meeting on emergency research studies.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 56 have been approved under OMB control number 0910–0130, the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. Modifications to these approved information collection requirements are underway or will be made at the time that each information collection is renewed. The Agency believes that this is appropriate because this guidance has only a minor impact on these existing collections of information.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: March 29, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–7846 Filed 4–1–11; 8:45 am]

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