

administrative, provider, and customer services process.

- Facilitate plans for IT Integration of data resources and data services.

- Coordinate policy analysis, development and execution for CMS.

- Build and maintain agency capacity to perform analysis of regional variation in the quality and cost of care.

- Conduct and manage surveys to capture information about beneficiary populations that our programs serve that is not available in the administrative data. This includes the Medicare Current Beneficiary Survey (MCBS) and the Medicare Health Outcomes Survey (HOS).

- Conduct and manage the Research Data Assistance Center (RESDAC), Research Data Distribution Center (RDDC) and Chronic Condition Warehouse (CCW) activities.

- Operationalize research-usable files for Medicare, Medicaid, and CHIP administrative data.

Dated: March 24, 2011.

Marilyn Tavenner,

Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Reunification Procedures for Unaccompanied Alien Children.

OMB No.: 0970-0278.

Description: Following the passage of the 2002 Homeland Security Act (Pub. L. 107-296), the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is charged with the care and placement of

unaccompanied alien children in Federal custody, and implementing a policy for the release of these children, when appropriate, upon the request of suitable sponsors while awaiting immigration proceedings. In order for ORR to make determinations regarding the release of these children, the potential sponsors must meet certain conditions pursuant to section 462 of the Homeland Security Act and the Flores v. Reno Settlement Agreement No. CV85 4544-RJK (C.D. Cal. 1997). The proposed information collection requests information to be utilized by ORR for determining the suitability of a sponsor/respondent for the release of a minor from ORR custody. The proposed instruments are the Sponsors Agreement to Conditions of Release, Verification of Release, Family Reunification Packet, and the Authorization for Release of Information.

Respondents: Sponsors requesting release of unaccompanied alien.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Verification of Release (UAC)	4,595	1	0.25	1,148.75
Authorization for Release of Information (Sponsor)	4,595	1	0.25	1,148.75
Family Reunification Packet (Sponsor)	4,595	1	1	4,595
Sponsors Agreement to Conditions of Release (Sponsor)	4,595	1	0.25	1,148.75
Verification of Release (Case Worker)	4,595	1	0.25	1,148.75
Authorization for Release of Information (Case Worker)	4,595	1	0.25	
Family Reunification Packet (Case Worker)	4,595	1	1	4,595
Sponsors Agreement to conditions of Release (Case Worker)	4,595	1	0.25	1,148.75

Estimated Total Annual Burden Hours: 16,082.50.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork

Reduction Project, *Fax:* 202-395-7285, *E-mail:*

OIRA_SUBMISSION@OMB.EOP.GOV,

Attn: Desk Officer for the Administration for Children and Families.

Dated: March 29, 2011.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011-7823 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-0474]

Maja S. Ruetschi: 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 Maja S. Ruetschi, MD for 5 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. Ruetschi 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. Ruetschi was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Ruetschi failed to respond. Dr. Ruetschi'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 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.

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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,