FR 6621), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0557. The approval expires on May 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: June 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15800 Filed 6–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0610]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 25, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–New and title ''Draft Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance: *Draft Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability—(OMB Control Number 0910–New)*

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic.'' In the **Federal Register** of December 16, 2008 (73 FR 76364), FDA published notice of the availability of a draft guidance of the same title. FDA anticipates that during an influenza pandemic, industry and FDA workforces may be reduced while reporting of adverse events related to widespread use of medical products indicated for the treatment and prevention of influenza may increase, although the extent of these possible changes is unknown. The revised draft guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic.

II. Revisions to the 2008 Draft Guidance

FDA is issuing a revised draft guidance that includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The revised draft guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events and a plan for the submission of stored reports that were not submitted within regulatory timeframes. The revised draft guidance recommends that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic do the following:

- Document the conditions that prevent them from meeting normal reporting requirements,
- Notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when these conditions exist and when the reporting process is restored, and
- Maintain records to identify what reports have been stored.

These recommendations represent collections of information under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) discussed in section IV of this document. In issuing this revised draft guidance, FDA considered all comments that were submitted in response to the December 2008 draft guidance. Most comments requested that greater clarity be provided in certain sections; FDA has revised these sections accordingly.

This draft guidance does not address monitoring and reporting of adverse events that might be imposed as a condition of authorization for products authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb–3). This draft guidance also does not address monitoring and reporting of adverse events as required by regulations establishing the conditions for investigational use of drugs, biologics, and devices. (See 21 CFR parts 312 and 812.)

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on postmarketing adverse event reporting for medical products and dietary supplements during pandemic influenza. 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.

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. Paperwork Reduction Act of 1995

Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they

conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance explains FDA's approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic, including an intent not to object to changes in the timing of submission of certain reports during some stages of the pandemic response. The Agency recommends that each firm's pandemic influenza COOP include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The draft guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) Maintain documentation of the conditions that prevent them from meeting normal reporting requirements; (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist and when the reporting process is restored; and (3) maintain records to identify what reports have been stored.

Based on the number of manufacturers that would be covered by the draft guidance, we estimate that approximately 5,000 firms will add the following to their COOP: (1) Instructions for reporting adverse events; and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year, and that each notification will takem approximately 8 hours to prepare and submit.

Concerning the recommendation in the draft guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements and also maintain records to identify what adverse event reports have been stored and when the reporting process is restored, we estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and that approximately 500 firms will each need approximately 8 hours to maintain the records. Therefore, the total recordkeeping burden that would result from the draft guidance would be 258,000 hours.

The draft guidance also refers to previously approved collections of information found in FDA's adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and part 803. These regulations contain collections of information that 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) and are approved under OMB control numbers 0910–0116, 0910–0291, 0910–0230, 0910–0308, 0910–0437, and 0910–0543. In addition, the draft guidance also refers to adverse event reports for nonprescription human drug products marketed without an approved application and dietary supplements required under sections 760 and 761 of the FD&C Act (21 U.S.C. 379aa and 379aa–1), which include collections of information approved under OMB control numbers 0910–0636 and 0910–0635.

In the **Federal Register** of January 7, 2011 (76 FR 1170), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA when normal reporting is not feasible	500	1	500	8	4,000

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Add adverse event reporting plan to COOP	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism	500	1	500	8	4,000

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]—Continued

	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Maintain records to identify what reports have been stored and when the reporting process was restored	500	1	500	8	4,000
Total					258,000

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

V. Electronic Access

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

Dated: June 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15799 Filed 6–23–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0472]

Timothy J. Rosio: 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 Timothy J. Rosio, M.D. 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. Rosio was convicted of misdemeanors 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. Rosio was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Rosio failed to respond. Dr. Rosio's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective June 24, 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), 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 October 18, 2007, Dr. Rosio pleaded guilty to one count of receipt and delivery of a misbranded drug in violation of 21 U.S.C. 331(c) and one count of misbranding of drugs held for sale in violation of 21 U.S.C. 331(k). On October 26, 2007, the U.S. District Court for the Eastern District of California entered judgment against Dr. Rosio for misdemeanor misbranding on those charges.

FDA's finding that debarment is appropriate is based on the misdemeanor convictions referenced herein. The factual basis for the convictions is as follows: Dr. Rosio was a licensed physician in the State of California. Between on or about February 23, 2004, and on or about August 26, 2004, in the Eastern District of California, Dr. Rosio received Botulinum Toxin Type A (TRI-toxin) from Toxin Research International (TRI), which had been shipped in interstate commerce, from Arizona to his clinic in the Eastern District of California. The TRI-toxin that he received was misbranded in that it lacked adequate directions for use in humans. The drug was not approved for use in humans by FDA. After receiving the unapproved drug, Dr. Rosio proffered the delivery and caused the delivery of the drug to patients, some on multiple occasions, in the form of injections, for pay and otherwise, in violation of 21 U.S.C. 331(c). Dr. Rosio additionally held the drug for sale as BOTOX, the FDA approved Botulinum Toxin Type A product. In so doing, Dr. Rosio acted in a way that caused the drug to be further misbranded by offering it for sale to the public under the name of another drug, specifically BOTOX, in violation of 21 U.S.C. 331(k).

As a result of his convictions, on February 16, 2011, FDA sent Dr. Rosio a notice by certified mail proposing to debar him 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. Rosio was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Rosio an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Rosio failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his 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 Timothy J. Rosio has