

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) debaring 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

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. Rosio 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* 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. Rosio, in any capacity during Dr. Rosio'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. Rosio provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Rosio during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Rosio for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2010-N-0472 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 13, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011-15737 Filed 6-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-E-0092]

Determination of Regulatory Review Period for Purposes of Patent Extension; XYZAL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XYZAL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory

review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product XYZAL (levocetirizine dihydrochloride). XYZAL is indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis, and the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XYZAL (U.S. Patent No. 5,698,558) from UCB Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration and that FDA determine the product's regulatory review period. In a letter dated June 1, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of XYZAL represented the first permitted commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for XYZAL is 305 days. Of this time, 0 days occurred during the testing phase of the regulatory review period, while 305 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* FDA has verified the applicant's claim that no investigational new drug application was submitted.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 25, 2006. The applicant claims July 24, 2006, as the date the new drug application (NDA) for Xyzal (NDA 22-064) was initially submitted. However, FDA records indicate that NDA 22-064 was submitted on July 25, 2006.

3. *The date the application was approved:* May 25, 2007. FDA has verified the applicant's claim that NDA 22-064 was approved on May 25, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension.