responses. Each submission is estimated to take 0.25 hour per response for a total of 0.75 hour, rounded to 1 hour.

Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: August 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20379 Filed 8–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0139]

Seth M. Yoser: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) (the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Seth M. Yoser, MD from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Yoser was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Dr. Yoser was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. In a May 20, 2010, letter to FDA, Dr. Yoser, through counsel, notified FDA that he acquiesces to debarment and therefore he has waived his right to a hearing concerning this action.

DATES: This order is effective May 20, 2010.

ADDRESSES: Submit applications for special 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, 240–632–6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On February 23, 2010, the U.S. District Court for the Western District of Tennessee entered judgment against Dr. Yoser for ten counts of mail fraud in violation of 21 U.S.C. 1341, twenty-three counts of unlicensed wholesale distribution of prescription drugs in violation of 21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(2)(A); and two counts of wire fraud in violation of 18 U.S.C. 1343.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for those convictions is as follows: Dr. Yoser was employed by the Eye Specialty Group (ESG), formerly known as the Vitreorentinal Foundation, and he was a partner of ESG from on or about June 2005, until approximately May 12, 2008. During the course of his employment and partnership with ESG, he performed treatments which included administering the prescription drugs Visudyne, Lucentis, and Avastin to treat Wet Aged Macular Degeneration.

Beginning on or about July 1, 2002, and continuing up to and including May 12, 2008, Dr. Yoser did knowingly devise a scheme and artifice to defraud ESG and Medicare in order to obtain money and property by means of false and fraudulent representation, billing, and pretense. As part of that scheme, he billed Medicare for Visudyne, Avastin, and Lucentis that he purportedly used to treat ESG patients but that he actually diverted from ESG patients and sold.

Beginning on or about April 14, 2004, through on or about October 2, 2007, in the Western District of Tennessee, and elsewhere, Dr. Yoser did knowingly engage in or cause the wholesale distribution in interstate commerce of the prescription drugs, Visudyne and Lucentis in Louisiana, Tennessee, Texas, and Arkansas without being licensed by those states in violation of 21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(2)(A).

As a result of his convictions, on April 19, 2010, FDA sent Dr. Yoser a notice by certified mail proposing to permanently debar him 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(a)(2)(B) of the act, that Dr. Yoser was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act. The proposal also offered Dr. Yoser 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. Yoser's attorney filed a May 20, 2010, response in which he stated that Dr. Yoser did not object to debarment and further clarified in writing that the May 20, 2010, letter intended to express Dr. Yoser's acquiescence to debarment. By acquiescing to debarment, as provided for in section 306(c)(2)(B) of the act, Dr. Yoser waived his opportunity for a hearing and any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the act, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Seth M. Yoser has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding and based on his notification of acquiescence, Dr. Yoser is permanently debarred 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 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 May 20, 2010, the date of the notification of acquiesce (see **DATES**) (see sections 306(c)(1)(B), (c)(2)(A)(ii), (c)(2)(B), and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), (c)(2)(B), and 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. Yoser, in any capacity during Dr. Yoser's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Yoser 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 act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Yoser during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Yoser for special termination of debarment under section 306(d)(4) of the act should be

identified with Docket No. FDA–2010–N–0139 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: August 10, 2010.

Howard R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2010–20418 Filed 8–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–P–0386]

Determination That DIASTAT (Diazepam Rectal Gel), 5 Milligrams/Milliliter, 10 Milligrams/2 Milliliter, 15 Milligrams/3 Milliliter, and 20 Milligrams/4 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DIASTAT (diazepam rectal gel) (DIASTAT), 5 milligrams (mg)/milliliter (mL), 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diazepam rectal gel, 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Lachman Consultant Services, Inc., submitted to FDA a citizen petition dated May 15, 2006 (Docket No. FDA–2006–P–0386),[1] under 21 CFR 10.30 requesting that the agency determine whether DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was withdrawn from sale for reasons of safety or effectiveness. DIASTAT (diazepam rectal gel) is the subject of approved NDA 20–648 held by Valeant Pharmaceuticals International (Valeant) (formerly held by Xcel Pharmaceuticals). DIASTAT (diazepam rectal gel) is an anticonvulsant agent indicated for use in the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity.

DIASTAT (diazepam rectal gel) was approved on July 29, 1997 (NDA 20–648). On September 15, 2005, FDA approved a supplement (NDA 20–648/S–008) for a new delivery system of DIASTAT (diazepam rectal gel), marketed under the trade name DIASTAT ACUDIAL. Following approval of DIASTAT ACUDIAL, Valeant discontinued marketing DIASTAT (diazepam rectal gel) (NDA 20–648) in the 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL strengths, and those strengths of the product were moved to the "Discontinued Drug Product List" section of the Orange Book. We note that the original DIASTAT (diazepam rectal gel) and DIASTAT ACUDIAL that replaced the original DIASTAT delivery system contain the same diazepam gel formulation. Thus, the original diazepam gel formulation is still being marketed, but in a different delivery system.

After considering the citizen petitions, other information submitted to the docket, and reviewing our records, FDA has determined that DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was withdrawn from sale for reasons of safety or effectiveness. Issues regarding the appropriateness of permitting ANDAs referencing the discontinued DIASTAT (diazepam rectal gel) to be marketed at the same time as DIASTAT ACUDIAL are being addressed in a separate docket (FDA–2006–P–0009).

Accordingly, the agency will continue to list DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

[1] This citizen petition was originally assigned docket number 2006P–0209. The number changed to FDA–2006–P–0386 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.