Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act—(OMB Control Number 0910-New)

As part of its commitments in PDUFA V. FDA has established a new review Program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applies to all New Molecular Entities (NMEs), New Drug Applications (NDAs), and original Biologics License Applications (BLAs) that are received from October 1, 2012, through September 30, 2017. The Program is described in detail in section II.B of the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (the ''Commitment Letter'') (available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the Program is an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The PDUFA V Commitment Letter specifies that the assessments be conducted by an independent contractor and that they include interviews of pharmaceutical manufacturers who submit NMEs, NDAs, and original BLAs to the Program in PDUFA V. The contractor for the assessments of the Program is Eastern Research Group, Inc. (ERG), and the statement of work for the assessments is available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf.*

Therefore, in accordance with the PDUFA V Commitment Letter, FDA proposes to have ERG conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing review transparency and communication during the review process. ERG will anonymize and aggregate sponsor responses prior to inclusion in the assessments and any presentation materials at public meetings. FDA will publish ERG's assessments (with interview results and findings) in the **Federal Register** for public comment.

In the **Federal Register** of February 19, 2013 (78 FR 11652), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA typically reviews approximately 40 to 45 NMEs, NDAs, and original BLAs per year. ERG will interview one to three sponsor representatives at a time for each application that receives a first-cycle action from FDA up to 135 sponsor representatives per year. Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	5	1	5	1.5	7.5
Interviews	135	1	135	1.5	202.5
Total					210

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

ERG will conduct a pretest of the interview protocol with five respondents. FDA estimates that it will take 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. We estimate that up to 135 respondents will take part in the post-action interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 202.5 hours. Thus, the total estimated annual burden is 210 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–10898 Filed 5–7–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0559]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 20, 2013, the Agency submitted a proposed collection of information entitled ''Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation'' 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 0910–0456. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on

the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10887 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0865]

David Freeman: 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 David Freeman 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 a finding that Mr. Freeman was convicted of introducing and delivering for introduction into interstate commerce of a misbranded drug, which relates to the development or approval, including the process for development or approval, of drug products and to the regulation of drug products under the FD&C Act. In addition, FDA determined that the type of conduct that served as the basis for Mr. Freeman's conviction undermines the process for the regulation of drugs. Mr. Freeman was given notice of the proposed debarment and an opportunity to request a hearing within the prescribed timeframe by regulation, but failed to respond. Mr. Freeman's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective May 8, 2013.

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, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., 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 development or approval, including the process for development or approval, of any drug product or otherwise 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 May 5, 2010, Mr. Freeman pleaded guilty to a misdemeanor offense of introducing and delivering for introduction into interstate commerce of a misbranded drug in violation of 21 U.S.C. 352(o), 331(a), and 333(a)(1). On July 7, 2011, the U.S. District Court for the District of Nevada entered judgment against Mr. Freeman for the misdemeanor offense of misbranding.

The FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: On July 23, 2008, Agents from Customs and Border Protection found two express mail packages at JFK International Mail Facility, each with a return address of Muhi Trading Corporation, Bahadur Manzil. A border search was conducted on both packages, which revealed 1,000 capsules labeled as the prescription drug omeprazole in each package. The pills were in blister packs on which was written ''Omega Biotech LTD.'' Mr. Freeman and his co-defendant, Mr. Ashley Brandon Foyle, were the importers of record for the packages. At all relevant times, neither Muhi Trading Corporation nor Omega Biotech LTD. were registered to manufacture, prepare, propagate, compound, or process drugs.

On January 20, 2009, an Agent with the Office of Criminal Investigations at FDA (OCI) conducted an undercover purchase of omeprazole through a Web site Mr. Freeman and Mr. Foyle used to sell their misbranded drugs. Mr. Freeman and Mr. Foyle repackaged omeprazole in their apartment and mailed it to the undercover agent. Laboratory testing of the tablets confirmed that the tablets contained omeprazole. On February 24, 2009, OCI agents searched Mr. Freeman and Mr. Foyle's residence and found unapproved drugs. The omeprazole pills that Mr. Freeman and Mr. Foyle imported, repackaged and sold had not been approved by or registered with FDA. At no time was Mr. Freeman and Mr. Foyle's apartment registered as a location where drugs could be manufactured, prepared, propagated, compounded, or processed.

As a result of his convictions, on October 31, 2012, FDA sent Mr. Freeman a notice by certified mail proposing to debar him 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 that Mr. Freeman was convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and to the regulation of drug products under the FD&C Act, and the conduct that served as the basis for Mr. Freeman's conviction undermines the process for the regulation of drugs because the introduction of misbranded drugs into interstate commerce is prohibited by the FD&C Act. The proposal also offered Mr. Freeman 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. Mr. Freeman 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 and Import Operations, 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 David Freeman has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Mr. Freeman 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. 355a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or