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

contractor, or otherwise uses the services of Mr. Freeman, in any capacity during Mr. Freeman's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 355b(a)(b)). If Mr. Freeman 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). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Freeman during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Freeman for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2012–N–0865 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: April 3, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2013–10973 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–2011–D–0722]

Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components'' dated May 2013. The guidance document recognizes the abbreviated donor history questionnaire and accompanying materials (aDHQ documents), version 1.3 dated December 2012, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations for collecting donor history information. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit 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: Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components'' dated May 2013. The guidance document recognizes the aDHQ documents, version 1.3 dated December 2012, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations. The aDHQ User Brochure defines a frequent donor as a donor who has previously donated two times using the full-length donor history questionnaire, one donation of which occurred within the previous 6 months. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate. The guidance also advises licensed manufacturers who choose to implement the acceptable aDHQ documents on how to report the manufacturing change consisting of the implementation of the aDHQ documents under 21 CFR 601.12.

In the **Federal Register** of October 24, 2011 (76 FR 65735), FDA announced the availability of the draft guidance of the same title dated October 2011. FDA received some comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: Referencing the most current version of the acceptable aDHQ documents, clarifying that the full-length and abbreviated questionnaires are designed to be implemented together, and editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2011.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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). The collections of information in 21 CFR 601.12 and Form FDA 356(h) have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 640.63 have been approved under OMB control number 0910–0116.