DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4046]

Charles Jeffrey Edwards: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Charles Jeffrey Edwards 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. Edwards was convicted, as defined in the FD&C Act, of two felony counts under federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Edwards was given notice of the proposed permanent debarment and was given an opportunity to request a hearing within the timeframe prescribed by regulation to show why he should not be debarred. As of November 15, 2019 (30 days after receipt of the notice), Mr. Edwards had not responded. Mr. Edwards's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 18, 2020.

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743 or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 20, 2018, Mr. Edwards was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act when judgment was entered against Mr. Edwards in the U.S. District Court for the Middle District of Tennessee, Nashville Division, after his plea of guilty, to one count of mail fraud in violation of 18 U.S.C. 1341 and one count of money laundering in violation of 18 U.S.C. 1957.

The factual basis for these convictions is as follows: as contained in Counts 2 and 27 of the Indictment, filed on January 17, 2013, to which Mr. Edwards pleaded guilty, from December 2006 through August 2009, Mr. Edwards, along with others, through Cumberland Distribution, Inc. (Cumberland), a company Mr. Edwards co-owned, was engaged in wholesale distribution of prescription drugs as defined by section 505(e) of the FD&C Act (21 U.S.C. 355(e)). Cumberland purchased millions of dollars of prescription drugs from unlicensed drug suppliers who were not authorized to distribute drugs under section 503 of the FD&C Act (21 U.S.C. 353). Mr. Edwards knew that these unlicensed suppliers often procured drugs from street level drug diverters who had obtained the drugs from persons with legitimate prescriptions. On many occasions, Mr. Edwards had drugs shipped to his shell companies, which Mr. Edwards used as passthroughs to create the appearance that his company was purchasing drugs from licensed suppliers, when in fact Mr. Edwards was purchasing drugs from unlicensed suppliers. Afterwards, Mr. Edwards had these drugs shipped to Cumberland's Nashville warehouse where they were repackaged and shipped to independent pharmacies around the country. Mr. Edwards also directed Cumberland employees to create false pedigree documents to make it appear that the diverted drugs were purchased from authorized sellers. The diverted drugs included drugs used to combat human immunodeficiency virus/acquired immunodeficiency syndrome; antipsychotic medications; antidepressants; blood pressure medications; diabetes medications, among others. Through the course of this scheme, Mr. Edwards' company had gross proceeds of approximately $58,984,912. Mr. Edwards and two others obtained profits of approximately $14,689,782.

As a result of these convictions, FDA sent Mr. Edwards by certified mail on October 9, 2019, a notice 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 FD&C Act, that Mr. Edwards was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Edwards 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Edwards received the proposal on October 16, 2019. Mr. Edwards did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Edwards has been convicted of two felonies under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Edwards is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). 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. Edwards, in any capacity during his 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 Mr. Edwards 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 from Mr. Edwards during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]''

(section 201(dd) of the FD&C Act (21 U.S.C. 321(dd)).

Any application by Mr. Edwards for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2019–N–4046 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies (21 CFR 10.20(a)). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05582 Filed 3–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Promoting the Rule of Law Through Improved Agency Guidance Documents

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services has received an extension to the deadline to comply with Executive Order 13891: *Promoting the Rule of Law Through Improved Agency Guidance Documents.* Executive Order 13891, through Subsections (a) and (b), requires the establishment of a new guidance portal and the rescission of any guidance documents that are not included in it, respectively. The Office of Management and Budget (OMB), through its implementing memorandum (*https://www.whitehouse.gov/wp-content/uploads/2019/10/M-20-02-Guidance-Memo.pdf*), has determined the deadlines for these subsections to be February 28, 2020. OMB granted the Department of Health and Human Services an extension for subsections (a) and (b) on February 27, 2020. The Department will establish its guidance portal by August 31, 2020.

A full copy of the extension letter can be found on the HHS website at, *https://www.hhs.gov/regulations/index.html.*

FOR FURTHER INFORMATION CONTACT: Samuel Shipley, Office of the Executive Secretary, at *Guidance@hhs.gov* or (202) 690–5627.

Dated: March 12, 2020.

Ann C. Agnew,

Executive Secretary, Department of Health and Human Services.

[FR Doc. 2020–05647 Filed 3–17–20; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; R13 Conference Grants.

Date: April 14, 2020.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH/NHLBI, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20814 (Virtual Meeting).

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20892, 301–827–7975, *reillymp@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 13, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05626 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Fellowships: Physiology and Pathobiology of the Vascular and Hematological Systems, March 27, 2020 8:00 a.m. to March 27, 2020, 8:00 p.m., The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854, which was published in the **Federal Register** on March 4, 2020, 85 FR 12799.

The meeting location is being held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting date and time remains the same. The meeting is closed to the public.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05637 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HHS–NIH–CDC–SBIR 2018–1 Phase II Topic 053: Effective Targeted Delivery of RNA-based Vaccines and Therapeutics.

Date: April 15, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of