members. In accordance with OMB Final Guidance published in the **Federal Register** on October 5, 2011 and revised on August 13, 2014, federally registered lobbyists may not serve on the Committee in an individual capacity to provide their own individual best judgment and expertise, such as RGEs members. This ban does not apply to lobbyists appointed to provide the Committee with the views of a particular group, organization, or association, such as Representative members.

Nominations

Nominations for membership on the Committee will be accepted until Thursday, February 9, 2023. There are two parts to submitting a nomination. First, complete the information requested via this electronic form *https://forms.gle/iuBc67bMYjo1xB5V6.* Next, email your CV or resume and a letter of endorsement from your organization or organization's leadership to *fscac@gsa.gov* with the subject line: FSCAC NOMINATION—[Nominee Name].

Federal agencies may nominate qualified federal employees for Federal membership.

Non-Federal nominees must meet the following criteria in accordance with the FedRAMP Authorization Act of 2022:

- Individuals representing an independent assessment organization; or
- Representatives from unique businesses that primarily provide cloud computing services or products, including at least 2 representatives from a small business concern (as defined by section 3(a) of the Small Business Act (15 U.S.C. 632(a))).

Brian Conrad,

FedRAMP Director (Acting)/Cybersecurity Program Manager, Federal Risk and Authorization Management Program, General Services Administration.

[FR Doc. 2023–01481 Filed 1–24–23; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—DD23–001, Birth Defects Study To Evaluate Pregnancy ExposureS (BD–STEPS); Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—DD23–001, Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS); March 28–29, 2023, 10 a.m.–5 p.m., EDT, Teleconference, in the original FRN. The meeting was published in the **Federal Register** on December 23, 2023, Volume 87, Number 246, page 78968.

The meeting is being amended to change the meeting date and time and should read as follows:

Date: March 29, 2023.

Time: 10 a.m.–6 p.m., EDT.

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Catherine Barrett, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–3, Atlanta, Georgia 30341–3717; Telephone: (404) 718–7664; Email: *CBarrett@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–01435 Filed 1–24–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 1009(d) of 5 U.S.C. 10, 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 117–286. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–23–002, Occupational Safety and Health Surveillance, Collaboration, Education, and Translation Review.

Date: March 22, 2023.

Time: 1 p.m.–3 p.m. EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Dan Hartley, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26506; Telephone: (304) 285–5812; Email: *DHartleycdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–01434 Filed 1–24–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0198]

Mark Moffett; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Mark Moffett and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Mr. Moffett 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. Moffett was convicted of multiple felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Mr. Moffett was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Moffett submitted a request for hearing but failed to file with the Agency information and analysis sufficient to create a basis for a hearing.

DATES: The order is applicable January 25, 2023.

ADDRESSES: Any application for termination of debarment by Mr. Moffett under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2022–N–0198. An application will be placed in the docket and, unless submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, *Rachael.Linowes@fda.hhs.gov,* 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act mandates permanent debarment 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 January 18, 2022, the U.S. District Court for the District of Massachusetts entered a judgment against Mr. Moffett, after a jury verdict, for nine counts of wire fraud in violation of 18 U.S.C. 1343 and five counts of aggravated identify theft in violation of 18 U.S.C. 1028A(a)(1). The court sentenced Mr. Moffett to 54 months in prison, $1,500 restitution payment, and upon his release from prison, a 36-month supervised release. The bases for his convictions stem from his employment with Aegerion Pharmaceuticals, Inc. (Aegerion), a pharmaceutical company located in Massachusetts, which held an approved drug application for the drug JUXTAPID (NDA 203858).

According to FDA's Office of Regulatory Affairs' (ORA) proposal to debar, discussed in more detail below, JUXTAPID was subject to risk evaluation and mitigation strategies (REMS) requirements due to JUXTAPID's risk of liver toxicity. JUXTAPID prescribers had to enroll in the JUXTAPID REMS program and attest that the patients to which they prescribed JUXTAPID had a diagnosis consistent with homozygous familial hypercholesterolemia (HoFH). JUXTAPID was only distributed by certain pharmacies and prior to dispensing, the pharmacy had to verify that the prescriber was certified in the JUXTAPID REMS program. Additionally, insurance companies would not pay for JUXTAPID if the patient did not have a HoFH diagnosis, so to facilitate insurance claims processing for patients, Aergerion established the patient access program (PAP), and the PAP personnel would call health insurance companies to obtain insurance coverage determinations for patients who had been prescribed JUXTAPID.

According to the proposal to debar, Mr. Moffett was a sales representative for Aegerion. Aegerion paid its sales representatives a base salary, plus bonuses for new prescriptions and bonuses for patients remaining on JUXTAPID over time. ORA found that Mr. Moffett schemed to enrich himself through the bonus program, and as part

of that scheme, from on or about January 2014 through at least October 2015, convinced doctors to prescribe JUXTAPID for statin intolerant patients who had not been diagnosed with HoFH. According to the proposal to debar, Mr. Moffett, among other actions:

1. Directed and caused JUXTAPID REMS forms, statements of medical necessity, and insurance forms to be submitted to insurance plans for JUXTAPID coverage by falsely representing that the prescriptions were for patients with HoFH;

2. Obtained fraudulent REMS forms from prescribers or obtained prescriptions from providers who had not treated relevant patients; and

3. Sent falsified prior authorizations or caused the falsified prior authorizations forms to be sent to PAP personnel, causing them to communicate the false information to insurance companies.

ORA's proposal to debar stated that Mr. Moffett received tens of thousands of dollars in bonuses for making purported sales of JUXTAPID.

By letter dated July 5, 2022, ORA notified Mr. Moffett of a proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application, based on the multiple convictions and underlying conduct outlined above. In addition to outlining the above information, ORA found that the wire fraud and aggravated identity theft felonies were for conduct relating to the regulation of drug products. ORA found that Mr. Moffett's actions undermine the process for the regulation of drugs because Mr. Moffett schemed to deceive health insurance companies into covering JUXTAPID for ineligible patients. Additionally, ORA found that Mr. Moffett's actions circumvented the REMS program, which subverted safety protocols put into place as part of JUXTAPID's approval. Therefore, ORA found that permanent debarment was appropriate.

By letter, dated August 4, 2022, Mr. Moffett submitted a document titled ''request for a hearing.'' This letter did not contain an actual request for a hearing, but the Director of the Office of Scientific Integrity (OSI) construed it as one. In addition, OSI granted Mr. Moffett an extension to submit any information or factual analyses in support of his request for a hearing until October 31, 2022. Mr. Moffett submitted another letter on October 11, 2022.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Mr. Moffett's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

Neither of Mr. Moffett's letters provides any information or factual analysis in rebutting the proposed findings in ORA's proposal to debar him. Instead, both letters state that he is currently appealing the convictions on which the proposed debarment is based. Specifically, in Mr. Moffett's October 11, 2022, letter, he requests a delay in the debarment proceeding until the conclusion of his appeal, and states that, ''if a hearing is scheduled before [he] receive[s] the results of [his] appellate appeal,'' he would like to know when the hearing will take place so that he may participate.

As previously explained in OSI's letter to Mr. Moffett granting him an extension, under section 306(l) of the FD&C Act, ''a person is considered to have been convicted of a criminal offense . . . (A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending.'' A pending appeal is therefore not a ground for postponing either ruling on a hearing request or conducting a hearing on a proposed debarment. However, if Mr. Moffett's appeal ultimately results in the convictions being overturned, he may seek termination of his debarment (see section 306(d)(B)(ii) of the FD&C Act).

Given that Mr. Moffett did not submit any information or factual analyses addressing the findings in ORA's proposal to debar him, Mr. Moffett has not raised a genuine and substantial issue of fact regarding whether he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Therefore, OSI denies Mr. Moffett's request for a hearing.

II. Findings and Order

The Chief Scientist, under section 306(a)(2) of the FD&C Act and under the authority delegated to her, finds that Mr. Mark Moffett has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing findings, Mr. Moffett is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 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**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Moffett, in any capacity during his period of 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. Moffett, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, 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. Moffett during his period of debarment.

Dated: January 19, 2023.

Namandje N. Bumpus,

Chief Scientist.

[FR Doc. 2023–01426 Filed 1–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0169]

Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes FDA's regulatory and enforcement priorities regarding compounding certain ibuprofen oral suspension products in outsourcing facilities for administration in hospitals and health systems.

DATES: The announcement of the guidance is published in the **Federal Register** on January 25, 2023.

ADDRESSES: You may submit either electronic or written comments on