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

Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–0169 for ''Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 comments 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ian Reynolds, Office of Compounding Quality and Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–7079.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately to bolster access to ibuprofen oral suspension products in hospitals and health systems during the current surge in respiratory infections, but it remains subject to comment in accordance with the Agency's good guidance practices.

This guidance describes the Agency's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products in outsourcing facilities for administration in hospitals and health systems. The United States is currently experiencing a surge in three viruses: Coronavirus Disease 2019 (COVID–19), respiratory syncytial virus (RSV), and influenza. Each of these viruses may produce fever in young children. FDA has received reports related to increased demand for pediatric fever-reducing medications, including ibuprofen oral suspension products. Further, FDA has received a number of reports related to hospitals and health systems experiencing challenges with obtaining these medications to use in the treatment of pediatric patients with fevers as well as for adults who are unable to swallow solid oral dosage forms (*e.g.* persons with feeding tubes). FDA is continually assessing the needs and circumstances related to the temporary policy set forth in this guidance, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw this policy as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the FD&C Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget

(OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collection of information for current good manufacturing practice requirements has been approved under OMB control number 0910–0139. The collections of information for adverse event reporting and human drug compounding under sections 503A and 503B of the FD&C Act have been approved under OMB control number 0910–0800. The collections of information for adverse event and product experience reporting under the MedWatch System has been approved under OMB control number 0910–0291.

III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01467 Filed 1–23–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1988]

Poornanand Palaparty; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is denying Poornanand Palaparty's (Dr. Palaparty's) request for a hearing and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. Palaparty for 3 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 Dr. Palaparty was convicted of a misdemeanor under Federal law for causing the introduction or delivery for introduction into interstate commerce of drugs that were misbranded under the FD&C Act. Additionally, FDA finds that the type of conduct underlying Dr. Palaparty's conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Dr. Palaparty's debarment, FDA considered the relevant factors listed in the FD&C Act. Dr. Palaparty failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable January 25, 2023.

ADDRESSES: Any application for termination of debarment by Dr. Palaparty under section 306(d) of the FD&C Act (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–2018–N–1988. Received applications will be placed in the docket and, except for those 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, 240–402–5931.

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 FDA finds that (1) the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the