(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

FD&C Act and (2) the type of conduct underlying the conviction undermines the process for the regulation of drugs under the FD&C Act.

On September 5, 2013, Dr. Palaparty pled guilty to a misdemeanor for introducing a misbranded drug into interstate commerce, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)). According to the criminal information to which Dr. Palaparty pled guilty, between July 4, 2004, and February 26, 2009, Dr. Palaparty, an oncologist, purchased and received prescription oncology drugs from a distributer located in Canada. Dr. Palaparty's actions caused the introduction into interstate commerce of drugs that were misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) because their labeling did not bear adequate directions for use. On November 12, 2014, the U.S. District Court for the Northern District of Ohio entered a judgment of conviction against Dr. Palaparty for his violation of section 301(a) and sentenced him to 1 year of probation.

By letter dated July 13, 2018, FDA's Office of Regulatory Affairs (ORA) proposed to debar him for 3 years from providing services in any capacity to a person that has an approved or pending drug product application and provided him with an opportunity to request a hearing. The proposal explained that FDA based the proposed debarment on his misdemeanor conviction. The proposal outlined findings concerning the four relevant factors that ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) the nature and seriousness of the offense, (2) the nature and extent of management participation in the offense, (3) the nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the FD&C Act or other Acts involving matters within FDA's jurisdiction. ORA found that the first two factors were unfavorable factors, and the last two factors were favorable for Dr. Palaparty. The notice concluded that the unfavorable factors outweighed the favorable factors and that a 3-year debarment was appropriate.

By letters dated August 10, 2018, and September 10, 2018, Dr. Palaparty, through counsel, requested a hearing on the proposal. Dr. Palaparty argues that FDA failed to consider certain facts underlying his conviction and therefore inappropriately weighed the factors under section 306(c)(3) of the FD&C Act. Dr. Palaparty primarily disputes ORA's assessment of the nature and seriousness of his offense. Separately, Dr. Palaparty requests that FDA consider a settlement between the Agency and himself as an alternative to debarment.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Dr. Palaparty'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 § 12.24(b) (21 CFR 12.24(b))).

Based on this review, the Chief Scientist concludes that Dr. Palaparty has failed to raise a genuine and substantial issue of fact requiring a hearing and that he has thus not justified a hearing. Given the undisputed factual findings in the proposal to debar, the Chief Scientist finds that a 3-year debarment period is appropriate.

II. Arguments

In the proposal to debar, ORA relied on the criminal information and the Government's sentencing memorandum in addressing the nature and seriousness of the offense. ORA noted that Dr. Palaparty ''continued purchasing misbranded drugs despite being notified by FDA on multiple occasions between 2004 and 2009 that foreign drug shipments destined for [his] office had been detained and appeared to be unlawfully marketed unapproved new drugs.'' ORA found that his ''conduct created a risk of injury to consumers by exposing patients to unapproved new drugs'' and that his conduct undermined the Agency's drug approval process and oversight of the manufacture, importation, and sale of drug products in interstate commerce in the United States.

In his request for a hearing, Dr. Palaparty disagrees with ORA's assertion that his conduct created a risk of injury to consumers by exposing patients to unapproved new drugs. Dr. Palaparty claims that Agency investigators ''told him that he could use the rest of the unapproved drugs as long as he did not order more of them.'' Dr. Palaparty suggests that ''[i]f these drugs truly posed a great risk to the public, the investigators would have instructed him to destroy the remaining drugs and would not have allowed him to use his remaining supply.''

Even if we assume what Dr. Palaparty asserts is true—that, on a given day in 2009, FDA agents told Dr. Palaparty he could use up the limited stock of unapproved new drugs he had in his office, instead of destroying the drugs—this alone would not establish that his overall pattern of conduct posed no risk to his patients and thus the public. Instead, his overall pattern of conduct over a 5-year period establishes that Dr. Palaparty willingly created a risk of injury to his patients. Dr. Palaparty does not dispute that, between 2004 and 2009, he placed multiple orders for unapproved oncology drugs, including Kytril, Gemzar, Oxaliplatin, Irinotecan, Camptosar, Zometa, Gemcitabine, Campto, Zoledronic Acid, and Carboplatin, manufactured outside of the United States. Additionally, Dr. Palaparty does not dispute that he continued purchasing these misbranded drugs despite being notified by FDA, on multiple occasions between 2004 and 2007, that these foreign drug shipments destined for his office had been detained and appeared to be unlawfully marketed unapproved new drugs. These undisputed facts, combined with the record underlying Dr. Palaparty's guilty plea, provide an ample basis for ORA to conclude that Dr. Palaparty should be debarred and that the ''nature and seriousness of [his] . . . offense'' is a factor that should be weighed against him in determining the length of his debarment.

Under § 12.24(b)(3), FDA will deny a hearing if ''the data and information submitted are insufficient to justify the factual determination urged, even if accurate.'' Applying this standard, Dr. Palaparty has offered allegations that, even if true, are insufficient to justify the larger factual determination he seeks: namely, that the larger pattern of his conduct posed no risk to his patients and the public and thus, by extension, did not interfere with FDA's ability to oversee the manufacture, importation, and sale of drug products in interstate commerce. Therefore, Dr. Palaparty fails to create an issue for hearing with respect to whether the nature and seriousness of the offense is an unfavorable factor in determining the appropriateness and length of debarment.

Dr. Palaparty does not object to the rest of ORA's findings in the proposal to debar. Regarding the nature and extent of management participation in the offense, Dr. Palaparty concedes that he held a position of authority in his medical practice as a licensed physician. Dr. Palaparty's admission to his position of authority warrants treating the management participation factor as an unfavorable factor in determining the appropriateness and

length of debarment. With respect to the third and fourth factors, he supports the findings that he mitigated the impact of his offenses on the public by fully cooperating with investigators and that he had no convictions involving matters within the jurisdiction of FDA.

Considering all the applicable factors listed in section 306(c)(3) of the FD&C Act, the Chief Scientist finds that Dr. Palaparty's conviction and underlying conduct warrant the 3-year debarment proposed by ORA. It is undisputed that Dr. Palaparty pled guilty to a serious misdemeanor offense by causing the introduction into interstate commerce of drugs that were misbranded by virtue of their unapproved status. It is undisputed that Dr. Palaparty had a managerial role, further cementing the serious nature of Dr. Palaparty's conduct. While Dr. Palaparty ultimately took voluntary steps to mitigate the effect on the public health from the unlawful conduct and does not have any previous criminal convictions related to matters within FDA's jurisdiction, those considerations do not outweigh the nature and seriousness of the conduct to a degree that would warrant a debarment period of less than 3 years. Therefore, a 3-year debarment is appropriate.

Separately, Dr. Palaparty requests that, in lieu of debarment by FDA, he enter into a settlement agreement with FDA whereby he would voluntarily agree to the terms of the proposed debarment for the proposed period of debarment and to not provide services in any capacity to a person that has an approved or pending drug product application. Dr. Palaparty appears to be proposing an informal resolution of this debarment matter. However, his request is now moot, given the foregoing findings, which establish that Dr. Palaparty has failed to justify a hearing with respect to ORA's proposal to debar him for 3 years, and support his debarment for the proposed time.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and authority delegated to her by the Commissioner of Food and Drugs, finds that Dr. Palaparty has been convicted of a misdemeanor under Federal law for causing the introduction into interstate commerce of prescription drugs that were misbranded under the FD&C Act and that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a 3-year debarment is appropriate.

As a result of the foregoing findings, Dr. Palaparty is debarred for 3 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 January 25, 2023, (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug application who knowingly uses the services of Dr. Palaparty, 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 Dr. Palaparty, 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 Dr. Palaparty during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: January 19, 2023.

Namandje N. Bumpus,

Chief Scientist.

[FR Doc. 2023–01419 Filed 1–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting Notice Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: HRSA published a document in the **Federal Register** of December 20, 2022, concerning a meeting of the National Advisory Council on the National Health Service Corps (NACNHSC). The document referenced the incorrect year. The meeting date erroneously stated a meeting will occur in November 2022 when it should state November 2023.

FOR FURTHER INFORMATION CONTACT: Diane Fabiyi-King, Designated Federal Official, Division of National Health Service Corps, HRSA, 5600 Fishers Lane, Room 14N23, Rockville, Maryland 20857; phone (301) 443–3609; or *NHSCAdvisoryCouncil@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 20, 2022, FR Doc. 2022–27532, page 77850, column 1, section two, bullet three, correct the ''November 14, 2022, 9:00 a.m.–5:00 p.m. ET and November 15, 2022, 9 a.m.–2 p.m. ET'' caption to read: November 14, 2023, 9 a.m.–5 p.m. ET and November 15, 2023, 9 a.m.–2 p.m. ET.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–01448 Filed 1–24–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board; Public Meeting

AGENCY: Administration for Strategic Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board), authorized under Section 319M of the Public Health Service (PHS) Act, as added by Section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by Section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act, will hold a virtual, public meeting on March 9, 2023. The NBSB provides expert advice and guidance to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, radiological, and nuclear threats, as well as other matters related to disaster preparedness and response. The Administration for Strategic Preparedness and Response (ASPR) manages and convenes the NBSB on behalf the Secretary of HHS. The NBSB public meeting will beginning at 11:00 a.m. Eastern time. A detailed agenda and Zoom registration instructions will be available on the ASPR website.

Procedures for Public Participation: The link to pre-register for the public meeting will be posted on the meeting website. The online meeting, which use a webinar format, will include American Sign Language interpretation and live captioning.

Members of the public may provide written comments or submit questions at any time via email to *NBSB@hhs.gov.* Additionally, the NBSB invites stakeholders to request up to seven minutes to address the Board in-person during the meeting. The Board wishes to hear from experts from relevant