Application Process (CAP), components of the FDA Industry Systems, or by contacting FDA for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. All information is currently submitted electronically using Forms FDA 3613d, 3613e, and 3613k. The eCATS Module is Form 3613k, where 3613e is the Certificate of Free Sale (*https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food*). All ''forms'' are electronic and part of the eCATS or CAP portal accessed via *https://www.access.fda.gov.* To view representations of the forms, instructions must be downloaded and are accessible through the following links: *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

While burden attributable to activities associated with export certificates issued for other FDA regulated products is accounted for and approved under OMB control number 0910–0498, this collection specifically supports information collection activity attributable to export certificates issued for human food and cosmetic products. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact FDA directly by email (*CFSANExportCertification@fda.hhs.gov*) or telephone (240–402–2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and instructions for requesting export certificates for food (Forms FDA 3613e and Form 3613k) are available online at *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

We are revising the information collection to include a web-based inquiry form, Form FDA 5077, entitled ''U.S. Department of Health and Human Services Food and Drug Administration Export Certification Inquiry,'' intended to facilitate processing by cross-referencing the request with existing Agency data. A mockup of the proposed electronic form is posted to the docket to solicit public comment. For food products, respondents may identify facilities using their Food Facility Registration number, FDA Establishment Identifier number, or a Data Universal Numbering System number. The system uses these identifiers to locate and auto-populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. For some applications, respondents can also upload product information via a spreadsheet, which reduces the time needed to enter product information, particularly for applications that include multiple products.

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured human food and cosmetic products to foreign countries that require export certificates.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of certificate	Form No. [2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cosmetics	FDA 3613d	66	3	198	0.5 (30 min.)	99
Food	FDA 3613e, 3613k	454	10	4,540	0.5 (30 min.)	2,270
Export Certification Inquiry	FDA 5077	520	18	9,360	0.25 (15 min.)	39
Total						2,408

[1] There are no operating and maintenance costs associated with this collection of information.
[2] All forms are submitted electronically via FDA Industry Systems.

Since our last review of the information collection, we have adjusted our estimate of the number of respondents downward. At the same time, we have increased the number of responses per respondent and added new Form FDA 5077. Cumulatively these activities result in an estimated burden increase of 39 hours and 9,360 responses annually.

Dated: May 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10606 Filed 5–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4785]

Gina Acosta: Final 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 (FD&C Act) permanently debarring Gina Acosta 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 Ms. Acosta was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Ms. Acosta was given notice of the proposed debarment and an opportunity to request a hearing to show why she should not be debarred. As of March 6, 2024 (30 days after receipt of the notice), Ms. Acosta has not responded. Ms. Acosta's failure to respond and request a hearing constitutes a waiver of Ms. Acosta's right to a hearing concerning this matter.

DATES: This order is applicable May 15, 2024.

ADDRESSES: Any application by Ms. Acosta for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time 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

- *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–2023–N–4785. 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. 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. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act 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 October 5, 2023, Ms. Acosta was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Texas-Beaumont Division, when the court accepted her plea of guilty and entered judgment against her for the felony offense of Conspiracy to Traffick in Drugs with Counterfeit Mark in violation of 18 U.S.C. 371 and 18 U.S.C. 2320(a)(4). The underlying facts supporting the conviction are as follows: as contained in the Second Superseding Indictment and the Factual Basis, between April 2014 until February 2021, Ms. Acosta was involved in a conspiracy with drug traffickers to distribute misbranded and counterfeit cough syrup. Specifically, Ms. Acosta worked for Woodfield Pharmaceutical, LLC as a packaging supervisor. Woodfield Pharmaceutical, LLC was a part of a group of pharmaceutical companies, which included Woodfield Pharmaceutical, LLC, a contract manufacturing company, and Woodfield Distribution. LLC, a third-party logistics company (collectively, ''Woodfield''). On April 25, 2014, Woodfield acquired Pernix Manufacturing, LLC (Pernix). Pernix had, in January 2014, entered into an agreement with Byron A. Marshall and his Drug Trafficking Organization (DTO) to copy and manufacture cough syrup according to the directions of Marshall and his associates.

Marshall was not licensed or authorized to distribute cough syrup and any background check of the personal information provided by Marshall to Pernix or later Woodfield would have revealed that he was not a licensed physician as he claimed. Initially, Marshall sought to copy Actavis Prometh VC with Codeine (Actavis). Actavis is a purple, peach-mint flavored prescription cough syrup that was in demand as a street drug. Marshall and his associates wanted to mass produce and traffic a counterfeit version of Actavis that contained promethazine, but not codeine. On April 24, 2014, Actavis Holdco US discontinued production of Actavis due to its widespread abuse by recreational drug users. A Pernix product-development scientist worked with Marshall and his associates to re-create the Actavis product without codeine and promethazine in order to re-create the syrup base, which is a necessary component of cough syrup. Marshall and his associates would add promethazine to the counterfeit substance prior to bottling and distribution in order to create the street drug. Marshall and his DTO also obtained counterfeited commercial-grade pharmaceutical labels designed to look exactly like the genuine labels for the prescription cough syrup from another supplier. Later in the conspiracy, Marshall and his DTO asked Woodfield employees to reformulate other cough syrup to use in their drug trafficking scheme to include Hi-Tech Promethazine Hydrocholoride and Codeine Phosphate Oral Solution (Hi-Tech) and Wockhardt Promethazine Syrup Plain (Wockhardt).

In her position within Woodfield, Ms. Acosta assisted in the packaging and delivery of the counterfeit cough syrup. In addition, between February 2019 through March 2021, Ms. Acosta was the principal point of contact between the owner of Woodfield, Adam Runsdorf, and the Marshall DTO. Ms. Acosta also was the principal conduit for cash from the Marshall DTO to Runsdorf.

From 2014 through February 2021, the conspiracy between the Marshall DTO produced and distributed, or attempted to produce and distribute, approximately 65,920 gallons of counterfeit cough syrup.

FDA sent Ms. Acosta, by certified mail, on January 30, 2024, a notice proposing to permanently debar her 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 Ms. Acosta was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal informed Ms. Acosta of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Acosta received the proposal and notice of opportunity for a hearing on February 5, 2024. Ms. Acosta failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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 Ms. Gina Acosta has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Acosta 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 in any capacity the services of Ms. Acosta during her 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 Ms. Acosta provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she 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 application from Ms. Acosta during her 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 sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation 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)'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: May 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10584 Filed 5–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD or Committee) will hold public meetings for the 2024 calendar year (CY). This notice supersedes the information about ACTPCMD's 2024 meetings found in the **Federal Register** notice dated December 15, 2023, Meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry.

DATES: ACTPCMD meetings will be held on:

- August 1, 2024, 8:00 a.m.–5:00 p.m. Eastern Time and August 2, 2024, 8:00 a.m.–3:00 p.m. Eastern Time, and
- Another 2024 meeting will be identified at a later date and announced at least 30 days before the meeting date through the **Federal Register**.

ADDRESSES: Meetings will be held in-person, by teleconference, and/or on a video conference platform. In-person meetings will be held at the HRSA Headquarters located at 5600 Fishers Lane, Rockville, Maryland, 20857 and will also be broadcast virtually on a video conference platform. For updates on how the meetings will be held, visit the ACTPCMD website 20 days before the date of the meeting, where instructions for joining meetings will be posted. For meeting information updates, go to the ACTPCMD website meeting page at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings.*

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Officer, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N102, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under Section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the committee, including findings and recommendations made by the committee concerning the activities under Section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary of Health and Human Services as well as the Chair and ranking members of the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce. ACTPCMD also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under title VII, part C of the PHS Act, and recommends appropriation levels for programs under this Part.

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2024 meetings, agenda items may include, but are not limited to, a full review of the many programs authorized under title VII, sections 747 and 748, of the PHS Act, discussions pertaining to tribal health issues, and potential recommendations updating the authorizing legislations for the programs. Refer to the ACTPCMD website listed above for all current and updated information concerning the CY 2024 ACTPCMD meetings, including agendas and meeting materials that will be posted 20 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACTPCMD should be sent to Shane Rogers using