submission program. FDA uses the information to evaluate whether a medical device may be reclassified from Class III into Class I or II, and if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device. Respondents to this information collection are private sector or other for-profit businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part 860, subpart D; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 860.210, 860.220, 860.230; De Novo requests—format, content, and acceptance elements.	79	1	79	182 hours	14,378
§ 860.230; FDA acceptance of request (*GFI Acceptance Checklist;* Appendix A) [1].	79	1	79		
§ 860.250; withdrawal of request	5	1	5	0.17 (10 mins.)	1
Total			84		14,379

[1] FDA assumes activities associated with review of the Acceptance Checklist are included in burden for submission of requests captured in row 1.

Our estimated burden for the information collection reflects an overall increase of 2,002 hours and a corresponding increase of 11 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: May 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11743 Filed 5–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4805]

Maria Anzures-Camarena: 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 (FD&C Act) permanently debarring Maria Anzures-Camarena 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. Anzures-Camarena 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. Anzures-Camarena 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. Anzures-Camarena has not responded. Ms. Anzures-Camarena's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable May 29, 2024.

ADDRESSES: Any application by Ms. Anzures-Camarena 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–4805. 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, 240–402–7500. 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 March 17, 2023, Ms. Anzures-Camarena 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 approximately April 2014 and February 2021 Ms. Anzures-Camarena was involved in a conspiracy with drug traffickers to distribute misbranded and counterfeit cough syrup. Specifically, Ms. Anzures-Camarena worked for Woodfield Pharmaceutical LLC as a packaging specialist. Woodfield Pharmaceutical LLC was a part of a group of pharmaceutical companies that 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 syrup base 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. Anzures-Camarena assisted in the packaging and delivery of the counterfeit syrup. In addition, when the Marshall DTO exhausted its available supply of promethazine, Ms. Anzures-Camarena was videoed, along with her supervisor, removing controlled substances from Woodfield's vault to deliver to the Marshall DTO. Later, Ms. Anzures-Camarena agreed with other Woodfield employees to create additional syrup base supply not authorized by Woodfield in order to sell that additional supply to Marshall and DTO at a reduced price in order to split the fee with other Woodfield employees, a practice Ms. Anzures-Camarena and other employees called, ''double batching.'' No records of the ''double batching'' were created.

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. Anzures-Camarena, by certified mail, on January 25, 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. Anzures-Camarena 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. Anzures-Camarena 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. Anzures-Camarena received the proposal and notice of opportunity for a hearing on February 5, 2024. Ms. Anzures-Camarena 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 Maria Anzures-Camarena 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. Anzures-Camarena 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. Anzures-Camarena 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. Anzures-Camarena 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. Anzures-Camarena 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 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11727 Filed 5–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2377]

Bayer HealthCare Pharmaceuticals, Inc., et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 28, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 019857	Cipro in Dextrose 5% in Plastic Container (ciprofloxacin) Injectable, 200 milligrams (mg)/100 milliliters (mL) and 400 mg/200 mL.	Bayer HealthCare Pharmaceuticals, Inc., 100 Bayer Blvd., Whippany, NJ 07981.
NDA 021158	Factive (gemifloxacin mesylate) Tablet, Equivalent to (EQ) 320 mg base.	LG Chem Ltd., C/O Parexel International, 2520 Meridian Parkway, Suite 200, Durham, NC 27713.
NDA 021473	Cipro XR (ciprofloxacin hydrochloride) Extended-Release Tablet, EQ 287.5 mg base.	Bayer HealthCare Pharmaceuticals, Inc.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of June 28, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on June 28, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11721 Filed 5–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1829]

Platform Technology Designation Program; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Platform Technology Designation Program for Drug Development.'' The purpose of this draft guidance is to provide details about the implementation of the Platform Technology Designation Program established by the PREVENT Pandemics Act. This draft guidance outlines eligibility factors for receiving a platform technology designation, potential benefits of receiving a designation, how to leverage data from designated platform technologies, how to discuss the planned designation request as part of a milestone meeting, the recommended content of a designation request submission, and the review timelines for a designation request. This draft guidance, when finalized, will represent the current thinking of FDA.

DATES: Submit either electronic or written comments on the draft guidance by July 29, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by July 29, 2024.

ADDRESSES: You may submit comments on any guidance 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