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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 28, 2024.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TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN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