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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 28, 2024.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TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN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

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–2024–D–1829 for ''Platform Technology Designation Program for Drug Development.'' 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 this draft guidance to the Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4162, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Melissa Furness, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4162, Silver Spring, MD 20993, 240–402–8912; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Platform Technology Designation Program for Drug Development.'' This draft guidance provides details about the implementation of the Platform Technology Designation Program under section 506K of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356k), which was established by section 2503 of the PREVENT Pandemics Act (2022) and enacted as part of Public Law 117–328. This draft guidance, when finalized, will outline criteria for receiving a platform technology designation, 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.

To determine eligibility for designation as a designated platform technology, FDA will first determine whether the technology qualifies as a platform technology. Under section 506K(h)(1) of the FD&C Act, a platform technology is a well understood and reproducible technology, which can may include a nucleic acid sequence, molecular structure, mechanism of action, delivery method, vector, or a combination of any such technologies that FDA determines to be appropriate, where it: (1) is incorporated in or utilized by a drug and is essential to the structure or function of such drug; (2) can be adapted for, incorporated into, or utilized by, more than one drug sharing common structural elements; and (3) facilitates the manufacture or development of more than one drug through a standardized production or manufacturing process or processes. A platform technology designation does not affect product eligibility for any expedited approval pathways if it is otherwise eligible. Sponsors of applications or emergency use authorization requests will also be allowed under certain circumstances to leverage data related to designated platform technologies previously submitted to FDA.

Under section 506K(b) of the FD&C Act, a platform technology is eligible for designation by FDA if: (1) it is incorporated in, or utilized by, an approved drug; (2) preliminary evidence demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the same party indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring

significant efficiencies to the drug development or manufacturing process and to the review process.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the ''Platform Technology Designation Program.'' 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

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Investigational New Drug Regulations

OMB Control Number 0910–0014—Revision

This information collection supports implementation of the Platform Technology Designation Program under section 506K of the FD&C Act. FDA recommends requesting designation of a platform technology during the investigational new drug phase of drug development for a planned new drug application (NDA) or biologics license application (BLA). Any request for platform technology designation will be reviewed by a team of FDA experts to evaluate the data and information submitted and to examine if the platform technology meets the definitional and eligibility criteria outlined in sections 506K(h)(1) and (b), respectively, of the FD&C Act. If the sponsor receives a platform technology designation, then information about the platform designation can be leveraged in subsequent applications from the same sponsor. A different sponsor may be able to leverage platform technology data if they receive a full right of reference to the leveraged data under a business arrangement with the originator of the platform technology. If a platform technology receives a platform technology designation, then FDA may take actions to expedite the development and review of any subsequent application submitted under section 505(b) of the FD&C Act or section 351(a) of the Public Health Service Act for a drug that uses or incorporates the designated platform technology pursuant to section 506K(e) of the FD&C Act.

We are issuing a draft guidance for industry entitled ''Platform Technology Designation Program for Drug Development,'' which outlines: (1) criteria for receiving a platform technology designation, (2) potential benefits of receiving a designation, (3) how to leverage data from designated platform technologies, (4) how to discuss a planned designation request as part of a milestone meeting, (5) the recommended content of a designation request submission, and (6) the review timelines for a designation request.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—PLATFORM TECHNOLOGY DESIGNATION PROGRAM

Section 506K of the FD&C act	Number of respondents	Number of records per respondents	Total annual records	Average burden per record	Total hours
Platform technology designation request; Guidance for industry section II.C	10	1	10	60	600

[1] There are no capital or operating and maintenance costs associated with the information collection.

Our updated figures are based on our experience with the information collection along with Agency data and reflect burden we attribute to the applicable reporting requirements and to those respondents we believe may incur such burden. These activities include submitting a request for platform technology designation to FDA. These estimates are based on historical metrics obtained during the first year of the Platform Technology Designation Program. We estimate that the number of platform technology designation requests received will increase after the publication of this guidance.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 314 relating to the submissions of NDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to the submissions of BLAs have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance 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: May 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11686 Filed 5–28–24; 8:45 am]

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