investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, XOFLUZA (baloxavir marboxil). XOFLUZA is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. Subsequent to this approval, the USPTO received a patent term restoration application for XOFLUZA (U.S. Patent No. 8,987,441) from Shionogi & Co., Ltd., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 23, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XOFLUZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for XOFLUZA is 985 days. Of this time, 801 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* February 14, 2016. The applicant claims March 2, 2016, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 14, 2016, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 24, 2018. FDA has verified the applicant's claim that the new drug application (NDA) for XOFLUZA (NDA 210854) was initially submitted on April 24, 2018.

3. *The date the application was approved:* October 24, 2018. FDA has verified the applicant's claim that NDA 210854 was approved on October 24, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 399 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17648 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3510]

Determination That CIPRO (Ciprofloxacin Hydrochloride) Tablet, Equivalent to 100 Milligrams Base, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CIPRO (ciprofloxacin hydrochloride (HCl)) tablet, equivalent to (EQ) 100 milligrams (mg) base, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for ciprofloxacin HCl tablet, EQ 100 mg base.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993–0002, 240–402–4191, *Ayako.sato@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

On October 22, 1987, FDA approved NDA 019537 for CIPRO (ciprofloxacin HCl) tablet, EQ 250 mg base, 500 mg base, and 750 mg base. On April 8, 1996, FDA approved a supplement to NDA 019537 to add the tablet, EQ 100 mg base, to treat acute uncomplicated cystitis in adult females to be supplied as a cystitis pack containing six 100 mg oral tablets with a dosing regimen of 100 mg twice daily for 3 days.

On May 18, 2005, FDA approved labeling revisions for NDA 019537, including updates to reflect that the 100 mg tablet drug product was no longer being marketed. CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, was moved from the ''Prescription Drug Product List'' to the ''Discontinued Drug Product List'' section of the Orange Book. Subsequently, the Agency made a safety and effectiveness determination that CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, was not discontinued for reasons of safety or effectiveness, which was later published in the **Federal Register** on October 1, 2019 (84 FR 52113). Since the Agency's initial safety and effectiveness determination, new information related to the safe and effective use of ciprofloxacin HCl tablet, EQ 100 mg base, for its indication has become available.

The resistance of *Escherichia coli* (*E. coli*), the main causative pathogen for acute uncomplicated cystitis, to ciprofloxacin has been increasing since CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis was removed from the labeling in 2005. The effectiveness of CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, and ciprofloxacin HCl tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis is not supported by the current ciprofloxacin susceptibility test interpretive criteria (STIC) (also known as break points),[1] established by the Clinical and Laboratory Standards Institute and recognized by FDA on June 10, 2019.[2] Recent pharmacokinetic/pharmacodynamic analyses conducted by FDA indicated that the dosage regimen of ciprofloxacin HCl tablet, 100 mg twice daily for 3 days may not be effective for the treatment of acute uncomplicated cystitis. A review of published literature also showed that more contemporary studies of the treatment of acute uncomplicated cystitis with ciprofloxacin were conducted with the dosage of 250 mg tablet twice daily or 500 mg extended-release tablet daily. A literature search produced no studies comparing the efficacy of ciprofloxacin 100 mg tablet twice daily versus ciprofloxacin 250 mg tablet twice daily or 500 mg extended-release tablet daily in treatment of acute uncomplicated cystitis. Finally, significant adverse reactions associated with the use of fluoroquinolones, including ciprofloxacin HCl, have been identified.[3]

On June 16, 2023, the Agency notified Bayer HealthCare Pharmaceuticals Inc. (Bayer) that it believed the potential problems associated with the drug product are sufficiently serious that the EQ 100 mg base strength product should be removed from the market pursuant to § 314.150(d) (21 CFR 314.150(d)). Bayer requested in a letter dated July 7, 2023, that FDA withdraw approval of the EQ 100 mg base strength product in NDA 019537 under § 314.150(d) and waived its opportunity for a hearing. FDA also notified application holders for ANDAs 075593, 075817, 075939, and 076794 on June 16, 2023, and for ANDA 076912 on June 21, 2023. FDA asked the ANDA holders to request withdrawal of approval under § 314.150(d) of the generic versions of ciprofloxacin HCl tablet, EQ 100 mg base, and to waive their opportunity for a hearing.

Consistent with requests from the relevant application holders, in the **Federal Register** of December 8, 2023 (88 FR 85636), FDA announced that it was withdrawing approval of the EQ 100 mg base strength product from NDA 019537 and ANDAs 075593, 075817, 075939, 076794, and 076912 for the treatment of acute uncomplicated cystitis, effective December 8, 2023. The Agency further noted that the withdrawal of approval is limited to CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, and ciprofloxacin HCl tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis and that other products approved in NDA 019537 for CIPRO (ciprofloxacin HCl) tablet or related ANDAs for ciprofloxacin HCl tablet (*e.g.,* the EQ 250 mg base, 500 mg base, or 750 mg base strength products) remain approved. Accordingly, the Agency has withdrawn approval of the EQ 100 base mg strength product from NDA 019537 and ANDAs 075593, 075817, 075939, 076794, and 076912 for the treatment of acute uncomplicated cystitis.[4]

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis from sale. We have also independently evaluated relevant literature and data. We have reviewed the available evidence. Given that the safe and effective use of ciprofloxacin HCl tablet, 100 mg twice daily for 3 days for the treatment of acute uncomplicated cystitis is not supported by its current STIC and considering the risks of serious adverse reactions along with the increased resistance of *E. coli* to ciprofloxacin, we have determined that CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, would not be considered safe and effective if it were introduced to the market today in the absence of new clinical studies to address relevant effectiveness concerns identified during our review.

Accordingly, under § 314.162 the Agency will remove Bayer's NDA 019537 for CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product. Likewise, the Agency will

[1] See Ciprofloxacin Oral, Injection products, available at *https://www.fda.gov/drugs/development-resources/ciprofloxacin-oral-injection-products.* Note *E. coli* is within the order of Enterobacterales.

[2] 21st Century Cures Act: Annual Compilation of Notices of Updates from the Susceptibility Test Interpretive Criteria web page; Request for Comments (85 FR 67353 at 67354 to 67355, October 22, 2020), recognizing on June 10, 2019, updated standard STIC for ciprofloxacin.

[3] Fluoroquinolone Antimicrobial Drugs Information, available at *https://www.fda.gov/drugs/information-drug-class/fluoroquinolone-antimicrobial-drugs-information.*

[4] Previously, a decade earlier, in a letter dated June 10, 2013, Plivia Inc., subsidiary of Teva Pharmaceuticals USA Inc., notified FDA that ciprofloxacin HCl tablet, EQ 100 mg base, EQ 250 mg base, EQ 500 mg base, and EQ 750 mg base, the subject of ANDA 076426, was being voluntarily withdrawn from the market and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of October 4, 2016, FDA announced it was withdrawing from approval ANDA 076426, held by Plivia Inc., under § 314.150(c), effective November 3, 2016 (81 FR 68427).

remove from the list of drug products published in the Orange Book, those drug products in ANDAs that used NDA 019537 CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base as their reference listed drug; these are Amneal Pharmaceuticals, LLC's ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075939; Dr. Reddy's Laboratories' ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075593; Watson Laboratories, Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076794; Rising Pharma Holdings, Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075817; Taro Pharmaceutical Industries Ltd.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076912; and Pliva Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076426.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17650 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2603]

Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Provider Survey of Topics Related to Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with a proposed study entitled ''Healthcare Provider Survey of Topics Related to Prescription Drug Promotion.''

DATES: Either electronic or written comments on the collection of information must be submitted by October 7, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–N–2603 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Provider Survey of Topics Related to Prescription Drug Promotion.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: 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.*

The draft survey instrument is available upon request from *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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