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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical 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 SEYSARA (sarecycline hydrochloride). SEYSARA is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for SEYSARA (U.S. Patent No. 8,318,706) from Paratek Pharmaceuticals, Inc., 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 SEYSARA 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 SEYSARA is 2,946 days. Of this time, 2,599 days occurred during the testing phase of the regulatory review period, while 347 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:* September 9, 2010. The applicant claims August 10, 2010, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 9, 2010, 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:* October 20, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for SEYSARA (NDA 209521) was initially submitted on October 20, 2017.

3. *The date the application was approved:* October 1, 2018. FDA has verified the applicant's claim that NDA 209521 was approved on October 1, 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 1,227 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: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27003 Filed 12–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4973]

Bayer HealthCare Pharmaceuticals Inc., et al.; Withdrawal of Approval of CIPRO (Ciprofloxacin Hydrochloride) Oral Tablet, Equivalent to 100 Milligrams Base, and Five Generic Ciprofloxacin Hydrochloride, Oral Tablet, Equivalent to 100 Milligrams Base Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is

withdrawing the approval of CIPRO (ciprofloxacin hydrochloride (HCl)) oral tablet, equivalent to (EQ) 100 milligrams (mg) base under new drug application (NDA) 019537 and five generic ciprofloxacin HCl, oral tablet, EQ 100 mg base products which referenced it as their basis of submission. The holders of the applications requested withdrawal of the 100 mg strength products and waived their opportunity for a hearing.

DATES: Approval is withdrawn as of December 8, 2023.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–4191.

SUPPLEMENTARY INFORMATION: On October 22, 1987, FDA approved NDA 019537 for CIPRO (ciprofloxacin HCl) oral tablet, EQ 250 mg, 500 mg, and 750 mg base. On April 8, 1996, FDA approved a supplement to NDA 019537 to add the oral 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. FDA approved the following generic ciprofloxacin HCl, oral tablet, EQ 100 mg base products under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) which identified as their reference listed drug (RLD) the 100 mg strength tablet approved in NDA 019537: [1]

- ANDA 075593 approved on June 9, 2004;
- ANDA 075817 approved on June 25, 2007;
- ANDA 075939 approved on March 3, 2005;
- ANDA 076794 approved on February 10, 2005; and
- ANDA 076912 approved on February 18, 2005.

On May 18, 2005, FDA approved labeling revisions for NDA 019537, including updates to reflect that the 100 mg oral tablet product was no longer being marketed. Subsequently, the Agency made a safety and effectiveness determination that CIPRO (ciprofloxacin HCl) oral 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, oral 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) oral tablet, EQ 100 mg base for the treatment of acute uncomplicated cystitis was removed from the product labeling in 2005. The effectiveness of CIPRO (ciprofloxacin HCl) oral tablet, EQ 100 mg base and ciprofloxacin HCl, oral tablet, EQ 100 mg base for the treatment of acute uncomplicated cystitis is not supported by the current ciprofloxacin Susceptibility Test Interpretive Criteria (STIC) (a.k.a., breakpoints),[2] established by the Clinical and Laboratory Standards Institute and recognized by FDA on June 10, 2019.[3] Recent pharmacokinetic/pharmacodynamic analyses conducted by FDA indicated that the dosage regimen of ciprofloxacin HCl oral 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 twice daily or 500 mg extended-release tablet daily. A literature search produced no studies comparing the efficacy of ciprofloxacin 100 mg twice daily versus ciprofloxacin 250 mg 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.[4] Given that the safe and effective use of ciprofloxacin hydrochloride tablets, 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, FDA believes that the potential problems associated with ciprofloxacin hydrochloride tablets, 100 mg are sufficiently serious that the product should be removed from the market under § 314.150(d) (21 CFR 314.150(d)).

On June 16, 2023, the Agency notified Bayer HealthCare Pharmaceuticals Inc. that it believes the potential problems associated with the drug are sufficiently serious that the 100 mg strength product should be removed from the market pursuant to § 314.150(d). Bayer requested in a letter dated July 7, 2023, that FDA withdraw approval of the 100 mg strength product in NDA 019537 under § 314.150(d) and waived its opportunity for a hearing.

FDA also notified abbreviated new drug applications (ANDAs) 075593, 075817, 075939 and 076794 on June 16, 2023, and 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 oral tablet, EQ 100 mg base, and to waive their opportunity for a hearing. In a letter dated June 26, 2023, Rising Pharma Holdings, Inc., requested that FDA withdraw approval of the 100 mg strength product in ANDA 075817 under § 314.150(d) and waived its opportunity for a hearing. In a letter dated June 30, 2023, Amneal Pharmaceuticals, LLC requested that FDA withdraw approval of the 100 mg strength product in ANDA 075939 under § 314.150(d) and waived its opportunity for a hearing. In separate letters dated July 7, 2023, Dr. Reddy's Laboratories and Watson Laboratories, Inc. requested that FDA withdraw approval of their 100 mg strength products in ANDA 075593 and in ANDA 076794, respectively, under § 314.150(d) and waived their opportunity for a hearing. In a letter dated July 12, 2023, Taro Pharmaceutical Industries, Ltd., requested that FDA withdraw approval of the 100 mg strength product in ANDA 076912 under § 314.150(d) and waived its opportunity for a hearing.

For the reasons discussed above, which Bayer and the ANDA holders do not dispute in their withdrawal request letters, and pursuant to the applicants' requests, FDA is withdrawing approval of the 100 mg strength product from one NDA and from the five ANDAs listed in the table below under § 314.150(d). This notice is limited to CIPRO (ciprofloxacin HCl) oral tablet, EQ 100 mg base and ciprofloxacin HCl, oral tablet, EQ 100 mg base for the treatment of acute uncomplicated cystitis. Other products approved in NDA 019537 for CIPRO (ciprofloxacin HCl) oral tablet or

[1] ANDA 076426 for ciprofloxacin HCl, oral tablet, EQ 100 mg was approved on June 15, 2005. In the **Federal Register** of October 4, 2016, FDA announced it was withdrawing the approval of ANDA 076426 upon request by the applicant under 21 CFR 314.150(c) (see 81 FR 68427, October 4, 2016).

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

[3] 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 67354–55, recognizing on June 10, 2019, updated standard susceptibility test interpretive criteria for ciprofloxacin.

[4] Fluoroquinolone Antimicrobial Drugs Information, available at *https://www.fda.gov/drugs/information-drug-class/fluoroquinolone-antimicrobial-drugs-information#:~:text=Fluoroquinolones%20are%20drugs%20approved%20for,such%20as%20colds%20or%20flu.*

related ANDAs for ciprofloxacin HCl, oral tablet (*e.g.,* the 250 mg base, 500 mg base, or 750 mg base strength products) remain approved. Distribution of CIPRO (ciprofloxacin HCl) oral tablet, EQ 100 mg base and ciprofloxacin HCl, oral tablet, EQ 100 mg base in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Application No.	Drug	Applicant
NDA 019537	CIPRO (ciprofloxacin HCl) oral tablet, EQ 100 mg base.	Bayer Healthcare Pharmaceuticals Inc., 100 Bayer Blvd., P.O. Box 915, Whippany, NJ 07981–0915.
ANDA 075593	Ciprofloxacin HCl, oral tablet, EQ 100 mg base.	Dr. Reddy's Laboratories Ltd., 107 College Rd. East, 2nd Floor Princeton, NJ 08540.
ANDA 075817	Ciprofloxacin HCl, oral tablet, EQ 100 mg base.	Rising Pharma Holdings, Inc., 2 Tower Center Blvd., Suite 1401A, East Brunswick, NJ 08816.
ANDA 075939	Ciprofloxacin HCl, oral tablet, EQ 100 mg base.	Amneal Pharmaceuticals, LLC, 50 Horseblock Rd., Brookhaven, NY 11719.
ANDA 076794	Ciprofloxacin HCl, oral tablet, EQ 100 mg base.	Watson Laboratories, Inc., 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 076912	Ciprofloxacin HCl, oral tablet, EQ 100 mg base.	Taro Pharmaceutical Industries, Ltd., 1600 Stewart Ave., Suite 604, Westbury, NY 11590.

Dated: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27015 Filed 12–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–E–0791]

Determination of Regulatory Review Period for Purposes of Patent Extension; VILTEPSO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VILTEPSO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 6, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 5, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 February 6, 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–2021–E–0791 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; VILTEPSO.'' 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