FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described 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.

Application No.	Drug	Applicant
ANDA 065125	Ceftriaxone for Injection, Equivalent to (EQ) 250 milligrams (mg) base/vial; EQ 500 mg base/vial; EQ 1 gram (g) base/vial; EQ 2 g base/vial.	Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202.
ANDA 078188	Irinotecan Hydrochloride Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL).	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 090088	Anastrozole Tablets, 1 mg	Do.
ANDA 206002	Bosentan Tablets, 62.5 mg and 125 mg	Alvogen Pine Brook, LLC, 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 212185	Chlorzoxazone Tablets, 375 mg and 750 mg	Glenmark Pharmaceuticals Inc., USA, 750 Corporate Dr., Mahwah, NJ 07430.
ANDA 212186	Amphetamine Sulfate Tablets, 5 mg and 10 mg	Do.
ANDA 213132	Arformoterol Tartrate Inhalation Solution, EQ 0.015 mg base/2 mL.	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 31, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on August 31, 2022 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: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16383 Filed 7–29–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1588; FDA–2020–E–1591; and FDA–2020–E–1592]

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

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 REBLOZYL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 30, 2022. 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 January 30, 2023. 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. Electronic comments must be submitted on or before September 30, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 Nos. FDA–2020–E–1588; FDA–2020–E–1591; and FDA–2020–E–1592 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; REBLOZYL.'' 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 § 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 biologic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product, REBLOZYL (luspatercept-aamt) indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusions. Subsequent to this approval, the USPTO received a patent term restoration application for REBLOZYL (U.S. Patent No. 8,058,229; 8,343,933; 8,361,957) from Acceleron Pharma Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of REBLOZYL 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 REBLOZYL is 3,041 days. Of this time, 2,822 days occurred during the testing phase of the regulatory review period, while 219 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 (21 U.S.C. 355(i)) became effective:* July 14, 2011. FDA has verified the applicant's claim that the date the investigational biologics license application became effective was on July 14, 2011.

2. *The date the application was initially submitted with respect to the human biologic product under section 351 of the Public Health Service Act (42 U.S.C. 262):* April 4, 2019. The applicant claims April 5, 2019, as the date the biologics license application (BLA) for REBLOZYL (BLA 761136) was initially submitted. However, FDA records indicate that BLA 761136 was submitted on April 4, 2019.

3. *The date the application was approved:* November 8, 2019. FDA has verified the applicant's claim that BLA 761136 was approved on November 8, 2019.

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 applications for patent extension, this applicant seeks 1,347 days, 1,361 days, or 1,548 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: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16385 Filed 7–29–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Meetings With Industry and Investigators on the Research and Development of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 31, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0731. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Meetings With Industry and Investigators on the Research and Development of Tobacco Products

OMB Control Number 0910–0731—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a new tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate as described in ''Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products,'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products*). This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. The original guidance issued in 2012 was revised for updating and clarity in July 2016.

In the guidance, the Agency discusses, among other things:

- What information FDA recommends persons include in a meeting request;
- How and when to submit a request; and
- What information FDA recommends persons submit prior to a meeting.

This guidance describes two collections of information: (1) the submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. FDA issued this guidance and the revisions consistent with FDA's good guidance practices regulations (21 CFR 10.115).

Meeting Requests: The guidance sets forth FDA's recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the following information be included in the meeting request:

1. Product name;
2. FDA-assigned Submission Tracking Number(s) of prior submissions (*e.g.,* premarket applications, meeting requests) for the product and relevant product version(s) (if applicable);
3. Product category (*e.g.,* cigarettes, smokeless tobacco) (if applicable);
4. Product use (indicate for consumer use or for further manufacturing);
5. Contact information for the authorized point of contact for the company requesting the meeting;
6. The topic of the meeting being requested (*e.g.,* a new tobacco product application, an application for permission to market a modified risk tobacco product, or investigational use of a new tobacco product);
7. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
8. A preliminary list of the specific objectives/outcomes expected from the meeting;
9. A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item;
10. A preliminary list of specific critical questions, grouped by discipline (*e.g.,* chemistry, clinical, nonclinical);
11. A list of all individuals who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator, including titles and responsibilities;
12. The date on which the meeting information package will be received by FDA; and
13. Suggested format of the meeting (*e.g.,* conference call, in-person meeting at FDA offices, video conference, or written response) and suggested dates and times for the meeting. Meetings are usually scheduled for 1 hour. FDA is proposing that a meeting request include the FDA-assigned submission tracking numbers of relevant product version(s), if applicable, to allow for FDA to reference such information to better assess and respond to the issues and questions raised in the meeting request.