

Cover Sheet.” Associated instructions may be found on our website at <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm>. The cover sheet (Form FDA 3397) need not be submitted for certain FDA-regulated products, e.g., generic drugs, and Whole Blood and Blood components for transfusion. The list of exempted products is included under the instructions to Form FDA 3397. Relatedly, sections 735 and 736 of the FD&C Act also provide for waiver, reduction, refund, and reconsideration requests. We developed the guidance document entitled “Guidance for Industry—User Fee Waivers, Reductions, and Refunds for Drug and Biological Products,” and Form FDA 3971 (Small Business Waivers and Refund Requests), which can be found

on our website at <https://www.fda.gov/media/131797/download>. We are revising the collection to include our current commitment goals, as set forth in the document “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,” also found on our website at <https://www.fda.gov/media/99140/download>. PDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. The commitment goals represent the product of FDA’s discussions with the regulated industry and public stakeholders, as mandated by Congress. FDA is committed to meeting these goals and to continuous operational improvements associated with PDUFA implementation. The commitment goals provide for the

development and issuance of topic-specific guidance. We maintain a searchable guidance database on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-document>. In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Prescription drug user fee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections 735 and 736 of the FD&C Act (PDUFA waivers, not including small business waivers) .....	112	1.68	189	17	3,213
Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers) .....	37	1	37	2	74
Reconsideration Requests .....	6	1.67	10	24	240
Appeal Requests .....	1	1	1	12	12
User Fee Cover Sheet Form FDA 3397 .....	174	1	174	0.5	87
				(30 minutes)	
Total .....			411		3,626

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C)) of the FD&C Act) will be 189, submitted by 112 different applicants; and that 37 respondents annually will each submit a small business waiver request. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 10 requests for reconsideration annually (including small business waiver reconsiderations), and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving 1 request annually for appeal of user fee waiver determination, and

assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA’s Center for Drug Evaluation and Research.

We assume 87 hours of burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) for submission of a new drug application or biologics license application.

The information collection reflects an overall increase since our last request for OMB review and approval. We attribute this to expected fluctuations in submissions to the Agency.

Dated: November 19, 2021.

**Lauren K. Roth,**  
Associate Commissioner for Policy.

[FR Doc. 2021–26079 Filed 11–29–21; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2020–E–2224]

**Determination of Regulatory Review Period for Purposes of Patent Extension; ZEPZELCA**

**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 ZEPZELCA 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 may submit either electronic or written comments and ask for a redetermination by January 31, 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 May 31, 2022. 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 January 31, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 31, 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 No. FDA-2020-E-2224 for Determination of Regulatory Review Period for Purposes of Patent Extension; ZEPZELCA. 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug 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 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 ZEPZELCA (lurbinectedin). ZEPZELCA is indicated for the treatment of adult patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received a patent term restoration application for ZEPZELCA (U.S. Patent No. 7,763,615) from Pharma Mar, S.A., and the USPTO requested FDA’s assistance in

determining this patent's eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZEPZELCA 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 ZEPZELCA is 4,170 days. Of this time, 3,987 days occurred during the testing phase of the regulatory review period, while 183 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:* January 16, 2009. The applicant claims January 14, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 16, 2009, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act:* December 16, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for ZEPZELCA (NDA 213702) was initially submitted on December 16, 2019.

3. *The date the application was approved:* June 15, 2020. FDA has verified the applicant's claim that NDA 213702 was approved on June 15, 2020.

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 1,826 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: November 19, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–26009 Filed 11–29–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Certificate of Origin (CBP Form 3229)

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security.

**ACTION:** 60-Day notice and request for comments; extension of an existing collection of information.

**SUMMARY:** The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

**DATES:** Comments are encouraged and must be submitted (no later than January 31, 2022) to be assured of consideration.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0016 in the subject line and the agency name. Please use the following method to submit comments:

*Email.* Submit comments to: [CBP\\_PRA@cbp.dhs.gov](mailto:CBP_PRA@cbp.dhs.gov).

Due to COVID–19-related restrictions, CBP has temporarily suspended its

ability to receive public comments by mail.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, telephone number 202–325–0056, or via email [CBP\\_PRA@cbp.dhs.gov](mailto:CBP_PRA@cbp.dhs.gov). Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at <https://www.cbp.gov/>.

#### SUPPLEMENTARY INFORMATION: CBP

invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

#### Overview of This Information Collection

*Title:* Certificate of Origin.

*OMB Number:* 1651–0016.

*Form Number:* CBP Form 3229.

*Current Actions:* Extension without change.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses.

*Abstract:* CBP Form 3229, Certificate of Origin, is used by shippers and