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, SUNOSI (solriamfetol hydrochloride) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Subsequent to this approval, the USPTO received a patent term restoration application for SUNOSI (U.S. Patent No. 8,440,715) from JAZZ Pharmaceutials, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 26, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SUNOSI 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 SUNOSI is 8,209 days. Of this time, 7,664 days occurred during the testing phase of the regulatory review period, while 545 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:* December 27, 1996. The applicant claims that December 17, 2009, is the date the investigational new drug application (IND) 107203 became effective. However, FDA's records indicate that the effective date was December 27, 1996, which was 30 days after FDA receipt of the applicant's earlier IND 52082.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 20, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for SUNOSI (NDA 211230) was initially submitted on December 20, 2017.

3. *The date the application was approved or the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act:* June 17, 2019. FDA has verified the applicant's claim that NDA 211230 was approved on March 20, 2019, and that the Drug Enforcement Administration issued an interim final rule controlling the product on June 17, 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 application for patent extension, this applicant seeks 1,386 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 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25297 Filed 11–18–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3031]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products.

DATES: Submit either electronic or written comments on the collection of information by January 18, 2022.

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 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 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–2018–N–3031 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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 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, including each proposed extension of an existing 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.

Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

OMB Control Number 0910–0749—Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

FDA issued a final rule on May 10, 2016 (81 FR 28707) that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the FD&C Act (*https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10688.pdf*). FDA expanded its authority over tobacco products by issuing another final rule entitled ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (Deeming rule; May 10, 2016, 81 FR 28974), deeming all products that meet the statutory definition of ''tobacco product,'' except accessories of the newly deemed tobacco products, to be subject to the FD&C Act (*https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf*). The Deeming rule, among other things,

subjected domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act's user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, the user fee final rule requires the submission of the information needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA.

As noted, FDA issued a final rule that requires domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the FD&C Act. The U.S. Department of Agriculture (USDA) had been collecting this information and provided FDA with the data the Agency needed to calculate the amount of user fees assessed to tobacco product manufacturers and importers. USDA ceased collecting this information in fiscal year 2015 (October 2014). USDA's information collection did not require OMB approval, per an exemption by Public Law 108–357, section 642(b)(3). Consistent with the requirements of the FD&C Act, FDA requires the submission of this information to FDA now instead of USDA. FDA took this action to ensure that the Agency continues to have the information needed to calculate, assess, and collect user fees from domestic manufacturers and importers of tobacco products.

Section 919(a) of the FD&C Act (21 U.S.C. 387s(a)) requires FDA to ''assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of the FD&C Act (chapter IX of the FD&C Act). The total amount of user fees to be collected for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and under section 919(a) FDA is to assess and collect a proportionate amount each quarter of the fiscal year. The FD&C Act provides for the total assessment to be allocated among the classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco product removed into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its share of the market for that tobacco product class.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1150.5(a), (b)(1), and (b)(2), and Form FDA 3852; General identifying information provided by manufacturers and importers of FDA regulated tobacco products and identification and removal information (monthly)	711	12	8,532	3	25,596
1150.5(b)(3); Certified copies (monthly)	711	12	8,532	1	8,532
1150.13; Submission of user fee information (identifying information, fee amount, etc.) (quarterly)	355	4	1,420	1	1,420
1150.15(a); Submission of user fee dispute (annually)	5	1	5	10	50
1150.15(d); Submission of request for further review of dispute of user fee (annually)	3	1	3	10	30
Total					35,628

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

FDA estimates that 711 entities will submit tobacco product user fees. The entity count was derived from aggregate data provided by the Alcohol and Tobacco Tax and Trade Bureau (TTB) and reflects that in 2021 there were 233 total permitted manufacturers and 478 permitted importers over all tobacco product types for which TTB assesses excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco).

The estimate of 711 respondents to provide the information requested from § 1150.5(a), (b)(1), and (b)(2) (21 CFR 1150.5(a), (b)(1), and (b)(2)), and Form FDA 3852 reflects both reports of no removal of tobacco products into domestic commerce and reports of removal of tobacco product into domestic commerce. FDA estimates it will take 3 hours for each of these submission types for a total of 25,596 hours. Under § 1150.5(b)(3), these respondents are also expected to provide monthly certified copies of the returns and forms that relate to the removal of tobacco products into domestic commerce and the payment of Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986 to FDA. We estimate that each monthly report will take 1 hour for a total of 8,532 hours. The estimate of 355 respondents to submit payment of user fee information under § 1150.13 (21 CFR 1150.13) reflects an average of half the number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. FDA estimates the quarterly submission will take approximately 1 hour for a total of 1,420 hours.

FDA estimates that five of those respondents assessed user fees will dispute the amounts under § 1150.15(a) (21 CFR 1150.15(a)), for a total amount of 50 hours. FDA also estimates that three respondents who dispute their user fees will ask for further review by FDA under § 1150.15(d), for a total amount of 30 hours. FDA has received nine dispute submissions since fiscal year 2015. Based on this data, the Agency does not believe we will receive more than five disputes and three requests for further reviews in the next 3 years.

FDA estimates the total annual burden for this collection of information is 35,628 hours. The estimated burden for the information collection reflects an overall increase of 2,648 hours. We attribute this adjustment to an increase in the number of entities submitting tobacco user fee information to FDA.

Dated: November 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25306 Filed 11–18–21; 8:45 am]

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