practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products—Content and Format.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 201 have been approved under OMB control number 0910–0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15161 Filed 7–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3031]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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, Health and Human Services (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 15, 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 0910–0749. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

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. 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's 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.

To make reporting requirements for this collection easier for respondents, FDA offers respondents the ability to provide their user fee submission information via an electronic form (Form FDA 3852). To learn more about the electronic submission process and download Form FDA 3852 respondents may go to: *https://www.fda.gov/tobacco-products/manufacturing/electronic-submissions-tobacco-products.*

In the **Federal Register** of November 19, 2021 (86 FR 64948), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 (2), and Form FDA 3852; General identifying information provided by manufacturers and importers of FDA regulated tobacco products and identification and removal information (monthly)	700	12	8,400	3	25,200
1150.5(b)(3); Certified copies (monthly)	700	12	8,400	1	8,400
1150.13; Submission of user fee information (identifying information, fee amount, etc.) (quarterly)	376	4	1,504	1	1,504
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					35,184

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

Recordkeeping burden hours for § 1150.5(a) and (b), Form FDA 3852, and § 1150.13 appearing in the notice published in the **Federal Register** on November 19, 2021, are obsolete due to fiscal year (FY) 2021 data. Table 1 of this document contains the updated estimates.

FDA estimates that entities will submit tobacco product user fee reports for approximately 700 Alcohol and Tobacco Tax and Trade Bureau (TTB) permits in a given month. The permit count was derived from aggregate data of active permit holders provided by the TTB and reflects that in FY21, there was an average of 234 total permitted manufacturers and 466 permitted importers reporting tobacco user fees over all tobacco product types for which TTB assesses excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco).

FDA estimates it will take 3 hours for each of these submission types for a total of 25,200 hours annually. 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 8,400 hours annually.

The estimate of 376 respondents required to submit payment of user fee information under § 1150.13 reflects an average across the 4 quarters for FY21 assessments issued to entities. FDA estimates the quarterly submission will take approximately 1 hour for a total of 1,504 hours annually.

FDA estimates that five of those respondents assessed user fees will dispute the amounts under § 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 35,184 hours. The estimated burden for the information collection reflects an overall decrease of 444 hours. We attribute this adjustment to a slight decrease in the number of entities submitting tobacco user fee information to FDA.

Dated: July 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15157 Filed 7–14–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0412]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to ScienCell Research Laboratories (ScienCell) for the ScienCell SARS–CoV–2 Coronavirus Real-time RT–PCR (RT–qPCR) Detection