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]

BILLING CODE 4164–01–P

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

Kit. FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization for the ScienCell SARS–CoV–2 Coronavirus Real-time RT–PCR (RT–qPCR) Detection Kit is revoked as of June 7, 2022.

ADDRESSES: Submit a written request for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On April 3, 2020, FDA issued an EUA to ScienCell for the ScienCell SARS–CoV–2 Coronavirus Real-time RT–PCR (RT–qPCR) Detection Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on June 5, 2020 (85 FR 34638), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on June 2, 2022, ScienCell requested revocation of, and on June 7, 2022, FDA revoked, the Authorization for the ScienCell SARS–CoV–2 Coronavirus Real-time RT–PCR (RT–qPCR) Detection Kit. Because ScienCell notified FDA that ScienCell decided to discontinue distribution of the ScienCell SARS–CoV–2 Coronavirus Real-time RT–PCR (RTqPCR) Detection Kit and requested FDA revoke the EUA for the ScienCell SARS-CoV–2 Coronavirus Real-time RT–PCR (RT–qPCR) Detection Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of ScienCell for the ScienCell SARS–CoV–2 Coronavirus Real-time RT–PCR (RTqPCR) Detection Kit. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

June 7, 2022

Yongjiang Daniel Li, Ph.D.
Associate Director, Molecular Biology Division
ScienCell Research Laboratories
1610 Faraday Avenue
Carlsbad, CA 92000
Re: Revocation of EUA200079

Dear Dr. Li:

This letter is in response to the request from ScienCell Research Laboratories ("ScienCell"), received on June 2, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit issued on April 3, 2020, and amended on June 5, 2020, September 22, 2020, and September 23, 2021. ScienCell indicated that it has decided to discontinue distribution of the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit and there is not any viable/non-expired product remaining in distribution.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because ScienCell has notified FDA that it has decided to discontinue distribution of the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit and requested FDA revoke the EUA for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200079 for the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: July 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15160 Filed 7–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular and Cellular Aspects of Obesity and Metabolic Disease.