scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 217188, for PAXLOVID (nirmatrelvir and ritonavir co-packaged tablets) for oral use, submitted by Pfizer, Inc. The proposed indication is treatment of mild-to-moderate coronavirus disease (COVID–19) in adults who are at high risk for progression to severe COVID–19, including hospitalization or death.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before March 9, 2023, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 2, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 3, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Frimpong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03971 Filed 2–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0465]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 the information collection provisions of our regulations requiring that the Agency receive prior notice before food is imported or offered for import into the United States.

DATES: Either electronic or written comments on the collection of information must be submitted by April 28, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 28, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–

2023–N–0465 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' 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, 10A–12M, 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.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285

OMB Control Number 0910–0520—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of FDA regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting Agency review after FDA has refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(l) of the FD&C Act; and § 1.285(i) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (Pub. L. 111–353) amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, ''any country to which the article has been refused entry.'' Advance notice of imported food allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain specific information that indicates prior refusals by any country and identifies the country or countries, the Agency may better identify imported food shipments that may pose safety and security risks to U.S. consumers.

This information collection enables FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States. Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial Environment (ABI/ACE) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at *https://www.access.fda.gov/.* Information the Agency collects in the prior notice submission includes: (1) the submitter and transmitter (if different from the submitter); (2) entry type and CBP identifier; (3) the article of food, including complete FDA product code; (4) the manufacturer, for an article of food no longer in its natural state; (5) the grower, if known, for an article of food that is in its natural state; (6) the FDA Country of Production; (7) the name of any country that has refused entry of the article of food; (8) the shipper, except for food imported by international mail; (9) the country from which the article of food is shipped or, if the food is imported by international

mail, the anticipated date of mailing and country from which the food is mailed; (10) the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; (11) the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; (12) the carrier and mode of transportation, except for food imported by international mail; and (13) planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA importer's entry notice, which has been approved under OMB control number 0910–0046. The information in an importer's entry notice is collected electronically via CBP's ABI/ACE at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 reflects FDA's estimate of the reduced burden for prior notice submitted through ABI/ACE in column 6 entitled ''Average Burden per Response.''

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information to FDA if information changes after the Agency has confirmed a prior notice submission for review (*e.g.,* if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after the Agency has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (iii)). In the event that FDA refuses admission to an article of food under section 801(m)(1) or the Agency places it under hold under section 801(l) of the FD&C Act, §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting FDA's review and the information required in a request for review. In the event that the Agency places an article of food under hold under § 801(l) of the FD&C Act, § 1.285(i) (21 CFR 1.285(i)) sets forth the procedure for, and the information to be included in, a post-hold submission.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions:						
Through ABI/ACE						
1.280 through 1.281	N/A	1,900	7,895	15,000,500	0.167 (10 minutes)	[2] 2,505,084
Through PNSI						
1.280 through 1.281	[3] 3540	13,000	231	3,003,000	0.384 (23 minutes)	1,153,152
Subtotal						3,658,236
Cancellations:						
Through ABI/ACE						
1.282	N/A	25,000	1	25,000	0.25 (15 minutes)	6,250
Through PNSI						
1.282 and 1.283(a)(5)	3540	50,000	1	50,000	0.25 (15 minutes)	12,500
Subtotal						18,750
Requests for Review and Post-hold Submissions:						
1.283(d) and 1.285(j)	N/A	1	1	1	8	8
1.285(i)	N/A	500	1	500	1	500
Subtotal						508
Total				18,079,001		3,677,494

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double counting, an estimated 396,416 burden hours already accounted for in the importer's entry notice information collection approved under OMB control number 0910–0046 are not included in the total.
[3] The term ''Form FDA 3540'' refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov/.*

Table 1 reflects the annual estimated reporting burden associated with the information collection. During the next 3 years, we estimate each respondent will need approximately 10 minutes per submission for a total of 15,000,500 annual submissions and 2,505,083.5 rounded up to 2,505,084 annual hours of burden. Similarly, we estimate 13,000 users submitting an average of 231 notices annually, requiring approximately 23 minutes per submission. Cumulatively, this totals 3,003,000 annual responses and 1,153,152 annual hours of burden.

Regarding cancellations of prior notices, we estimate 25,000 respondents averaging 1 cancellation annually and requiring 15 minutes to do so. Cumulatively this totals 25,000 annual submissions and 6,250 annual hours of burden. Similarly, we estimate 50,000 registered users submitting an average of 1 cancellation annually and requiring 15 minutes to do so. Cumulatively this totals 50,000 annual responses and 12,500 annual hours of burden.

We estimate that we will receive one submission annually under § 1.283(d) or § 1.285(j) over the next 3 years. It takes approximately 8 hours to prepare a submission, which results in 8 hours of burden.

Finally, for an average of 500 post-hold submissions annually, we estimate it will take respondents 1 hour to prepare the written notification described in § 1.285(i)(2)(i), for a total of 500 annual burden hours.

Based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years, we are adjusting our burden estimate for this information collection by increasing the number of responses and total burden. The number of responses has increased by 3,146,589 responses (from 14,932,412 to 18,079,001). The total burden has increased by 769,918 hours (from 2,907,576 to 3,677,494). We attribute the adjustment to an increase in the number of responses.

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03991 Filed 2–24–23; 8:45 am]

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