DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4259]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export Certificates for Food and Drug Administration Regulated 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 export certificates for FDA regulated products.

DATES: Either electronic or written comments on the collection of information must be submitted by December 26, 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 December 26, 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–4259 for ''Export Certificates for FDA Regulated 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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Export Certificates for FDA Regulated Products

OMB Control Number 0910–0498—Extension

This information collection supports the implementation of FDA statutory and regulatory provisions and related forms. Sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e) and 382) pertain to the export of FDA-regulated products and are intended to ease restrictions on exportation. The provisions also require the Agency to issue written export certifications within 20 days of any request. To offset Agency resource expenditures for processing certifications requests, the statute provides that FDA may charge firms a fee not to exceed $175.

The information collection contains five FDA forms (Form FDA 3613, 3613a, 3613b, 3613c, and 3613g) related to exporting FDA-regulated products. A description of each form is provided in table 1. To obtain a fillable PDF file of each form, visit *https://www.fda.gov/about-fda/reports-manuals-forms/forms,* and type ''3613'' in the search field. We accept online applications for export certificates for specific product areas through web-based application systems. To access these web-based application systems, visit the FDA Industry Systems web page at *http://www.access.fda.gov.* We are in the process of revising the forms to remove paper submission instructions for specific product areas where paper submissions are no longer accepted.

To learn more about how to complete these forms and general information for specific product areas, visit: *https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/fda-forms-certificates-exporting* and *https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/how-complete-fda-export-certificate-forms; https://www.fda.gov/drugs/human-drug-exports/electronic-certificates-pharmaceutical-product-general-information; https://www.fda.gov/medical-devices/importing-and-exporting-medical-devices/exporting-medical-devices;* and *https://www.fda.gov/animal-veterinary/import-exports/exporting-animal-feed-and-animal-drugs.*

TABLE 1—CERTIFICATES AND USES

Type of Certificate/Form FDA#	Use
Form FDA 3613: ''Supplementary Information Certificate to Foreign Government Requests''. ''Exporter's Certification Statement Certificate to Foreign Government''. ''Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)''.	For the export of products legally marketed in the United States
Form FDA 3613a: ''Supplementary Information Certificate of Exportability Requests''. ''Exporter's Certification Statement Certificate of Exportability''.	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act
Form FDA 3613b: ''Supplementary Information Certificate of a Pharmaceutical Product''. ''Exporter's Certification Statement Certificate of a Pharmaceutical Product''.	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license
Form FDA 3613c: ''Supplementary Information Non-Clinical Research Use Only Certificate''. ''Exporter's Certification Statement (Non-Clinical Research Use Only)''.	For the export of a non-clinical research use only product, material, or component that is not intended for human use and which may be marketed in, and legally exported from the United States under the FD&C Act
Form FDA 3613g: ''Certificate to Foreign Government for Devices Not Exported from the United States''.	For the shipping of devices not exported from the United States that may be legally marketed in the United States.

Appropriate centers within FDA review product information submitted by firms in support of the firms' certificate requests. We rely on respondents to certify their compliance with all applicable requirements of the FD&C Act both at the time the certification request is submitted to FDA and at the time the certification is submitted to the respective foreign government. Information regarding FDA's Export Certificates may be found on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certificates.*

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research (CBER)	2,344	1	2,344	1	2,344
Center for Devices and Radiological Health	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research (CDER)	6,981	1	6,981	1	6,981
Center for Veterinary Medicine (CVM)	1,618	1	1,618	1	1,618
Total					33,293

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

Based on a current evaluation of the information collection, we have adjusted the burden estimate. Our estimated burden for the information collection reflects an overall increase of 2,687 hours and a corresponding increase of 2,687 responses. CDER has instituted electronic certificates of pharmaceutical product (eCPP) to streamline the application process and reduce the time from receipt to issuance of export certificates. The increase in CDER export application requests is attributable to the implementation of the eCPP and an increase in drug exports. The increase is offset by a decrease in CVM and CBER export applications attributable to consequences of the pandemic.

Dated: October 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23561 Filed 10–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board Public Meeting

AGENCY: Administration for Strategic Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB) will publicly meet using an online format on Thursday, November 30, 2023 (12:30 to 4:00 p.m. ET). Notice of the meeting is required under section 10(a)(2) of the Federal Advisory Committee Act (FACA). The NBSB provides expert advice and guidance to the U.S. Department of Health and Human Services (HHS) regarding current and future chemical, biological, radiological, and nuclear threats, as well as other matters related to disaster preparedness and response. The Administration for Strategic Preparedness and Response (ASPR) manages and convenes the NBSB on behalf the Secretary of HHS. The NBSB will discuss and vote on two sets of recommendations related to COVID–19 pandemic lessons, *Project NextGen* vaccine and therapeutic products, and disaster preparedness training.

Procedures for Public Participation: The public and expert stakeholders are invited to observe the meeting. Pre-registration (Zoom) is required. Anyone may submit questions and comments to the NBSB by email (*NBSB@hhs.gov*) before the meeting. American Sign Language translation and Communication Access Real-Time Translation will be provided.

Representatives from industry, academia, health professions, health care consumer organizations, non-federal government agencies, or community-based organizations may request up to seven minutes to speak directly to the Board. Requests to speak to the Board will be approved in consultation with the Board Chair and based on time available during the meeting. Requests to speak to the NBSB during the public meeting must be sent to *NBSB@hhs.gov* by close of business on November 23, 2023. Please provide the full name, credentials, official position(s), and relevant affiliations for the speaker and a brief description of the intended topic. Presentations that contain material with a commercial bias, advertising, marketing, or solicitations will not be allowed. A meeting summary will be available on the NBSB website post-meeting.

FOR FURTHER INFORMATION CONTACT: CAPT Christopher Perdue; NBSB Designated Federal Official, (202) 480–7226; *NBSB@HHS.GOV.*

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2023–23532 Filed 10–24–23; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0092]

Agency Information Collection Activities; Revision of a Currently Approved Collection: E-Verify Program

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until November 24, 2023.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2007–0023. All submissions received must include the OMB Control Number 1615–0092 in the body of the letter, the agency name and Docket ID USCIS–2007–0023.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on June 29, 2023, at 88 FR 42091, allowing for a 60-day public comment period. USCIS received two comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0023 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*