DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4259]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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, the 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 April 1, 2024.

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 0910–0498. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Export Certificates for FDA Regulated Products

OMB Control Number 0910–0498—Revision

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 FDA forms (Form FDA 3613, 3613a, 3613b, 3613c, 3613f, and 3613g) related to exporting FDA-regulated products. A description of each form is provided in table 1.

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 and Form FDA 3613f: ''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.

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 *https://www.access.fda.gov.* For additional information on export certification processing for specific product areas refer to the following websites: *https://www.fda.gov/vaccines-blood-biologics/compliance-actions-biologics/exporting-cber-regulated-products,* (CBER); *https://www.fda.gov/medical-devices/importing-and-exporting-medical-devices/exporting-medical-devices* (CDRH); *https://www.fda.gov/drugs/human-drug-exports/electronic-certificates-pharmaceutical-product-general-information* (CDER); and *https://www.fda.gov/animal-veterinary/import-exports/exporting-animal-feed-and-animal-drugs* (CVM).

We are transitioning to a requirement for electronic submission of the forms related to medical device products. Therefore, we revised FDA Forms 3613, 3613a, 3613c, and 3613g to remove the paper submission instructions in the portions of the forms related to medical device products.

We developed the guidance document ''FDA Export Certification'' (August 2021) which is intended to provide a general description of FDA export certification to industry and foreign governments. The guidance document is available from our website at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm.* Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115,

which provide for public comment at any time.

In the **Federal Register** of October 25, 2023 (88 FR 73349), 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 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Forms FDA 3613, 3613a, 3613b, 3613c, 3613f, and 3613g; submission to 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 (CDRH)	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research (CDER)	9,396	1	9,396	1	9,396
Center for Veterinary Medicine (CVM)	1,618	1	1,618	1	1,618
Total	24,533		24,533		35,708

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

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. Further 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.*

The estimated burden for the information collection reflects an overall adjustment increase of 5,102 hours and a corresponding increase of 5,102 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 COVID–19 pandemic. In addition, revised form instructions related to medical device products are included in the information collection request.

Dated: February 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04155 Filed 2–28–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2936 and FDA–2022–E–2937]

Determination of Regulatory Review Period for Purposes of Patent Extension; GEMTESA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for GEMTESA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by April 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 27, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 29, 2024. 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