

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>.

Dated: December 21, 2017.

Eric D. Hargan

Acting Secretary of Health and Human Services.

[FR Doc. 2018-03402 Filed 2-16-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration-Regulated Products: Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by March 22, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0498. Also include the FDA docket number found in brackets in the heading of this document.

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

Export of Food and Drug Administration-Regulated Products: Export Certificates

OMB Control Number 0910-0498—Extension

In April 1996, the FDA Export, Reform, and Enhancement Act of 1996 (FDAERA) (Pub. L. 104-134) amended sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e) and 382). It was

designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of FDAERA provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of sections 801(e) and 802 or other requirements of the FD&C Act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to \$175 for the certifications. In January 2011, section 801(e)(4)(A) was amended by the FDA Food Safety Modernization Act (Pub. L. 111-353) to provide authorization for export certification fees for food and animal feed.

This section of the FD&C Act authorizes FDA to issue export certificates for regulated food, animal feed, pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the FD&C Act. FDA has developed various types of certificates that satisfy the requirements of section 801(e)(4)(B) of the FD&C Act. Four of those certificates are discussed in this notice: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, and (4) Non-Clinical Research Use Only Certificates. FDA has updated the certificates as part of the proposed collection of information to account for the amendment authorizing export certification fees for food and animal feed. Table 1 lists the different certificates and details their uses:

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
“Supplementary Information Certificate to Foreign Government Requests”.	For the export of products legally marketed in the United States.
“Exporter’s Certification Statement Certificate to Foreign Government”	
“Exporter’s Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)”.	
“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.
“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.
“Supplementary Information Non-Clinical Research Use Only Certificate”.	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act.
“Exporter’s Certification Statement (Non-Clinical Research Use Only)”	

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their request to the appropriate

center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to the appropriate offices.

In the **Federal Register** of November 27, 2017 (82 FR 56031), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. The burden hours have decreased from the previous approval.

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	2,651	1	2,651	1	2,651
Center for Devices and Radiological Health	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research	3,680	1	3,680	1	3,680
Center for Veterinary Medicine	1,925	1	1,925	1	1,925
Total	30,606

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

Dated: February 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-03346 Filed 2-16-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-E-1187]

Determination of Regulatory Review Period for Purposes of Patent Extension; MAESTRO RECHARGEABLE SYSTEM

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 MAESTRO RECHARGEABLE SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 23, 2018. 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 20, 2018. 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. Electronic comments must be submitted on or before April 23, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 23, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2016-E-1187 for “Determination of Regulatory Review Period for Purposes of Patent Extension; MAESTRO RECHARGEABLE SYSTEM.” 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.

- **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