are able to request a user fee payment refund or transfer online at *https://www.fda.gov/forindustry/userfees/default.htm.* This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

In the **Federal Register** of April 29, 2021 (86 FR 22669), 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
User Fee Payment Refund Request—Form FDA 3913	474	1	474	0.40 (24 minutes)	190
User Fee Payment Transfer Request—Form FDA 3914.	194	1	194	0.25 (15 minutes)	49
Total					239

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

The current burden estimate shows a decrease of approximately 642 hours for this information collection over that reported previously. The change reflects increased experience by the respondents to correctly submit fee payments and increased sophistication in use of the forms to request payments made in error. The use of the forms for the user fee programs (*e.g.,* Prescription Drug User Fees, Generic Drug User Fees, Animal Drug User Fees, Animal Generic Drug User Fees, Biosimilar Drug User Fees) are optional.

In addition, new information technology applications have more accurately calculated the number of registrants of drug facilities/food facilities/medical device facilities/medicated feed facilities, and we have therefore revised the number of respondents to the information collection.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21421 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Safety; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 November 1, 2021.

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 0910–0760. 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.

Food Safety; Federal-State Food Regulatory Program Standards

OMB Control Number 0910–0760—Revision

This information collection supports implementation of FDA's Federal-State Regulatory Program Standards, part of our National Integrated Food Safety System (IFSS) Programs and Initiatives. For more information we invite you to visit our website at: *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives.* In the United States, Federal and State governments work cooperatively to ensure the safety of food intended for both human and animal consumption. Part of this effort includes developing and maintaining uniform review criteria by which to assess food safety. FDA has established and maintains a number of program standards aimed at improving the safety evaluation for certain food products including manufactured foods and animal feed. Similarly, we are establishing regulatory program standards for eggs and have developed the ''Eggs Regulatory Program Standards'' (ERPS). The ERPS is intended for use by State and local regulatory officials and identifies 10 elements we believe are essential to the effective regulatory assessment of egg safety. States are encouraged to build systems that are sustainable and implement plans corresponding to the IFSS.

In the course of their normal duties, State, local, Territorial, and Tribal governments collect information pertaining to compliance with the respective State, local, Territorial, and Tribal food safety requirements within their jurisdictions. Although content and format of the information collected may vary, these activities are a usual and customary part of routine regulatory oversight. Respondents to the information collection are State, local, Territorial, and Tribal regulatory agencies.

The ERPS offers forms, worksheets, and templates to help respondents assess and meet the program elements identified and discussed. Respondents are not required to use the sample collection instruments included in the ERPS, however all data elements should be submitted to FDA and supporting documentation retained. The ERPS is

not intended to address any performance appraisal processes that any State, local, Territorial, or Tribal agency may use to evaluate its employees' performance. Funding opportunities are available to respondents who choose to implement the ERPS; however, these opportunities are limited and contingent upon the availability of funds, and are available to those respondents who currently have an egg inspection contract with FDA and thus are subject to auditing. A copy of the ERPS has been posted to FDA–2021–N–0341 and is available at *https://www.regulations.gov.*

In the **Federal Register** of May 14, 2021 (86 FR 26528), 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 RECORDKEEPING BURDEN [1]

Type of respondents; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	10	10	100	50	5,000

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

Based on our experience with similar information collection, we estimate an initial 10 respondents will participate in the ERPS, and assume an average of 50 burden hours per response is necessary for the attendant recordkeeping and submission of data elements to FDA. We expect participation in the ERPS to increase. Finally, upon submission of the Information Collection Request, we are correcting an inadvertent calculation error in the total burden hours as displayed on page 26530, in Table 1, in our 60-day notice in the **Federal Register** of May 14, 2021 (86 FR 26528).

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21367 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0843]

Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice entitled ''Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments'' that appeared in the **Federal Register** of August 9, 2021. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for the notice published on August 9, 2021 (86 FR 43553). Submit either electronic or written comments by November 30, 2021.

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 November 30, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2021. 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–2021–N–0843 for ''Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments.'' 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