listed on the ICSSL are safe. Respondents will have already independently collected samples at a given location/time (our request is for an additional sample to be collected and sent to FDA for analysis) and, in some cases (for requested existing analytical results), conducted tests associated with information submitted as part of samples and analytical results. Regarding the collection of samples, FDA will provide shipping materials for transport and will bear any shipping costs.

The information collection also includes respondents providing to FDA documents demonstrating compliance with the NSSP. When a competent authority in another country conducts an evaluation to determine whether the U.S. food safety control measures for bivalve molluscan shellfish are equivalent to its own system of controls, the competent authority may require FDA to provide information and records demonstrating compliance with the provisions of the NSSP. Only those firms that comply with the NSSP would be permitted to export bivalve molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. FDA uses the information collection to support the export of U.S. shellfish to countries whose competent authorities have determined the U.S. system of food safety controls to be equivalent to their own system of controls by demonstrating that the exporter follows the U.S. system of controls specified in the NSSP.

For example, to implement the European Commission's (EC) determination that the U.S. system of food safety controls for raw bivalve molluscan shellfish is equivalent to the European Union's (EU) system of controls, the EC requires FDA to provide documentation collected from NSSP-participating shellfish control authorities for firms seeking to export raw molluscan shellfish to the EU. This documentation includes, but is not limited to:

- a list of growing areas with an approved classification;
- the most recent sanitary survey for each growing area with an approved classification; and
- the most recent inspection report for each dealer seeking to export bivalve molluscan shellfish to the EU.

The examples above are illustrative. Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We provide respondents with information about the specific documentation that is required for each equivalence assessment. For those competent authorities that recognize the U.S. system as equivalent, additional documentation may be needed to implement that determination.

Form FDA 3038 may be submitted on paper or submitted electronically by State or international officials. These officials securely log into a shellfish shippers account to fill out Form FDA 3038 electronically. The information obtained from the form has been entirely automated. The forms transmitted by the States, after approval by an FDA official, are entered into an FDA computer database program that allows the addition, deletion, download, and generation of the Interstate Certified Shellfish Shippers List, published monthly in PDF format, and may be updated daily when new data is available.

Description of Respondents: Respondents to this collection are participating State regulatory agencies and foreign nations.

In the **Federal Register** of December 19, 2024 (89 FR 103832), we published a 60-day notice soliciting comment on the proposed collection of information. Although one comment was received offering support for FDA's efforts in ensuring the safety of shellfish, it referenced proposed rulemaking and therefore we are clarifying that this notice pertains to FDA information collection activities subject to OMB review and clearance under the PRA of 1995.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer's Certificate.	3038	40	57	2,280	0.10 (6 minutes)	228
Submission of NSSP Compliance Documentation.	N/A	13	1	13	0.25 (15 minutes)	3
Submission of Samples and Analytical Results.	N/A	35	2	70	0.50 (30 minutes)	35
Total						266

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

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 35 hours and 70 responses due to the program change of collecting samples and analytical results. We attribute the burden change to an increase in responses. This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years.

Dated: June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11328 Filed 6–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3370]

Post-Warning Letter Meetings Under Generic Drug User Fee Amendments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Post-Warning Letter Meetings Under GDUFA.'' This guidance provides information on the implementation of the Post-Warning Letter Meeting process for certain drug manufacturing facilities, a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to the reauthorization of the Generic Drug User Fee Amendments (GDUFA), as described in ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (GDUFA III commitment letter). Specifically, this guidance describes the process detailed in the GDUFA III commitment letter for how an eligible facility may request a Post-Warning Letter Meeting with FDA regarding the facility's ongoing remediation efforts to address current good manufacturing practice (CGMP) deficiencies described in a warning letter, how to prepare and submit a complete meeting package, and how FDA intends to conduct the Post-Warning Letter Meeting.

DATES: The announcement of the guidance is published in the **Federal Register** on June 20, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–D–3370 for ''Post-Warning Letter Meetings Under GDUFA.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rebecca Frey-Cooper, Office of Manufacturing Quality, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–4127, *Rebecca.Frey-Cooper@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Post-Warning Letter Meetings Under GDUFA.'' This guidance provides information on the implementation of the Post-Warning Letter Meeting process, a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to the reauthorization of GDUFA, as described in the GDUFA III commitment letter. Specifically, this guidance describes the process in the GDUFA III commitment letter for how an eligible facility may request a Post-Warning Letter Meeting with FDA regarding the facility's ongoing remediation efforts to address CGMP deficiencies described in a warning letter, how to prepare and submit a complete meeting package, and how FDA intends to conduct the Post-Warning Letter Meeting.

This guidance finalizes the draft guidance entitled ''Post-Warning Letter Meetings Under GDUFA'' issued on September 5, 2023 (88 FR 60686). FDA considered comments received on the draft guidance as the guidance was finalized. Though no significant changes were made, the final guidance includes editorial changes made for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current

thinking of FDA on ''Post-Warning Letter Meetings Under GDUFA.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M–25–20, and finds this action to be deregulatory in nature.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 210 and 211 pertaining to CGMP has been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 11 for electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information pertaining to the submissions of GDUFA III commitment letter, meetings related to generic drug development, and the Generic Drug User Fee Program have been approved under OMB control number 0910–0727.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11323 Filed 6–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2185]

Determination of Regulatory Review Period for Purposes of Patent Extension; EXEM FOAM

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 EXEM FOAM 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 human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by August 19, 2025. 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 December 17, 2025. 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 August 19, 2025. 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–2020–E–2185 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; EXEM FOAM.'' 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