the specific manufacturing operations conducted at the establishment.

We believe the required electronic MEI can be consolidated to appear in a single location to facilitate the complete, timely, and accurate review of all manufacturing establishments involved in the preparation of a drug or biological product. This will help to eliminate the inclusion and/or maintenance of potentially outdated and erroneous information that could be retrieved from other Agency files and will enable proper identification and timely evaluation of manufacturing establishments for conformance with requirements, including current good manufacturing practices.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The draft guidance discusses the electronic submission of MEI contained in an NDA, ANDA, or BLA to the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research by specifying the format for the electronic submission of such submissions. The information collection discussed in the guidance is contained in our NDA and ANDA regulations (part 314) and approved under OMB control number 0910–0001, and our BLA regulations (part 601) and approved under OMB control number 0910–0338. Currently, MEI is submitted as part of the existing application form, Form FDA 356h, and is approved by OMB under control number 0910–0338.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31626 Filed 12–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0879]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

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 January 30, 2017.

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 0910–0354. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products—21 CFR part 123

OMB Control Number 0910–0354—Extension

FDA regulations in part 123 (21 CFR part 123) mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (4)).

Certain provisions in part 123 require that processors and importers of seafood collect and record information. The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor's HACCP plan (*e.g.,* the values for processing times, temperatures, acidity, etc., as observed at critical control points). The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided.

HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 123.12 requires that importers of seafood products take affirmative steps and maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. These records are also to be made available for review by FDA as provided in § 123.12(c).

The time and costs of these recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and on the nature of the equipment or instruments required to monitor critical control points. The burden estimate in table 1 includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. The estimate also does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors. Consequently, the estimates in table 1

account only for information collection and recording requirements attributable to part 123.

Description of respondents: Respondents to this collection of information include processors and importers of seafood.

In the **Federal Register** of July 26, 2016 (81 FR 48816), 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]

21 CFR Section [2]	Number of recordkeepers	Number of records per recordkeeper [3]	Total annual records	Average burden per recordkeeping [4]	Total hours
123.6(a), (b), and (c); Prepare hazard analysis and HACCP plan.	50	1	50	16	800
123.6(c)(5); Undertake and prepare records of corrective actions.	15,000	4	60,000	.30 (18 minutes)	18,000
123.8(a)(1) and (c); Reassess hazard analysis and HACCP plan.	15,000	1	15,000	4	60,000
123.12(a)(2)(ii); Verify compliance of imports and prepare records of verification activities.	4,100	80	328,000	.20 (12 minutes)	65,600
123.6(c)(7); Document monitoring of critical control points.	15,000	280	4,200,000	.30 (18 minutes)	1,260,000
123.7(d); Undertake and prepare records of corrective actions due to a deviation from a critical limit.	6,000	4	24,000	.10 (6 minutes)	2,400
123.8(d); Maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing.	15,000	47	705,000	.10 (6 minutes)	70,500
123.11(c); Maintain sanitation control records	15,000	280	4,200,000	.10 (6 minutes)	420,000
123.12(c); Maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123.	4,100	80	328,000	.10 (6 minutes)	32,800
123.12(a)(2); Prepare new written verification procedures to verify compliance of imports.	41	1	41	4	164
Total					1,930,264

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] These estimates include the information collection requirements in the following sections:
§ 123.16—Smoked Fish—process controls (see § 123.6(b));
§ 123.28(a)—Source Controls—molluscan shellfish (see § 123.6(b));
§ 123.28(c) and (d)—Records—molluscan shellfish (see § 123.6(c)(7)).
[3] Based on an estimated 280 working days per year.
[4] Estimated average time per 8-hour work day unless one-time response.

We base this hour burden estimate on our experience with the application of HACCP principles in food processing. Further, the burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry. The hour burden of HACCP recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the size of the facility and complexity of the HACCP control scheme (*i.e.,* the number of products and the number of hazards controlled); the daily frequency that control points are monitored and values recorded; and also on the extent that data recording time and cost are minimized by the use of automated data logging technology. The burden estimate does not include burden hours for activities that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (§ 1240.60) is a customary and usual practice among seafood processors.

Based on our records, we estimate that there are 15,000 processors and 4,100 importers. We estimate that 50 processors will undertake the initial preparation of a hazard analysis and HAACP plan (§ 123.6(a), (b), and (c)). We estimate the burden for the initial preparation of a hazard analysis and HAACP plan to be 16 hours per processor for a total burden of 800 hours.

We estimate that all processors (15,000 processors) will undertake and keep records of four corrective action plans (§ 123.6(c)(5)) for a total of 60,000 records. We estimate the burden for the preparation of each record to be .30 hours for a total burden of 18,000 hours. We estimate that all processors (15,000 processors) will annually reassess their hazard analysis and HACCP plan (§ 123.8(a)(1) and (c)). We estimate the burden for the reassessment of the hazard analysis and HAACP plan to be 4 hours per processor for a total burden of 60,000 hours.

We estimate that all importers (4,100 importers) will take affirmative steps to verify compliance of imports and prepare 80 records of their verification activities (§ 123.12(a)(2)(ii)) for a total of 328,000 records. We estimate the burden for the preparation of each record to be .20 hours for a total burden of 65,600 hours.

We estimate that all processors (15,000 processors) will document the monitoring of critical control points (§ 123.6(c)(7)) at 280 records per processor for a total of 4,200,000 records. We estimate the burden for the preparation of each record to be .30 hours for a total burden of 1,260,000 hours.

We estimate that 40 percent of all processors (6,000 processors) will maintain records of any corrective actions taken due to a deviation from a critical limit (§ 123.7(d)) at 4 records per

processor for a total of 24,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 2,400 hours.

We estimate that all processors (15,000 processors) will maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing (§ 123.8(d)) at 47 records per processor for a total of 705,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 70,500 hours.

We estimate that all processors (15,000 processors) will maintain sanitation control records (§ 123.11(c)) at 280 records per processor for a total of 4,200,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 420,000 hours.

We estimate that all importers (4,100 importers) will maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123 (§ 123.12(c)). We estimate that 80 records will be prepared per importer for a total of 328,000 records. We estimate the burden for the preparation of each record to be .10 hours for a total burden of 32,800 hours.

We estimate that 1 percent of all importers (41 importers) will require new written verification procedures to verify compliance of imports (§ 123.12(a)(2)). We estimate the burden for preparing the new procedures to be 4 hours per importer for a total burden of 164 hours.

Dated: December 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31424 Filed 12–28–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2495]

Submission of Warning Plans for Cigars; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Submission of Warning Plans for Cigars.'' The guidance will help those involved in the manufacture, distribution, and sale of cigars in the United States understand the new cigar warning plan requirements under FDA's final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The guidance reiterates the health warning statements and display and distribution requirements that should be provided in cigar warning plans and will help persons determine who should submit a warning plan, when a plan must be submitted, and what information should be included when submitting a plan.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–D–2495 for ''Submission of Warning Plans for Cigars; Guidance for Industry.'' 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 Division of Dockets Management 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 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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New