comparable approved radiopharmaceutical that produces for an identified individual patient a clinical difference, the determination is documented on the prescription or order in writing by either (1) the prescribing practitioner, or (2) the compounder, reflecting a conversation with the prescribing practitioner. The compounder maintains records of the prescription or order documenting this determination.

We estimate that annually a total of approximately 10 compounders (''No. of Respondents'' in table 1, line 1) will consult a prescriber to determine whether he or she has made a determination that the compounded radiopharmaceutical has a change that produces a clinical difference for an identified individual patient as compared to the comparable approved radiopharmaceutical. We estimate that compounders will document this determination on approximately 250 prescriptions or orders for compounded radiopharmaceuticals ''Total Annual Disclosures'' in table 1, line 1). We estimate that the consultation between the compounder and the prescriber and noting this determination on each prescription or order that does not already document this determination will take approximately 3 minutes per prescription or order.

A compounder also maintains records of prescriptions or orders noting the determination that a prescriber has determined that the compounded radiopharmaceutical has a change that produces a clinical difference for an identified individual patient. We estimate that the compounder will take approximately 2.1 hours to maintain the records of 250 prescriptions or orders documenting the prescriber's determination of clinical difference (''Total Hours'' in table 2). We estimate that maintaining such records will take approximately 30 seconds per prescription or order.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of reporting	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Consultation between the compounder and prescriber or health care facility, and the notation on the prescription or order documenting the prescriber's determination of clinical difference.	10	25	250	3 minutes	12.5

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of reporting	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
Maintenance of records of prescriptions or orders documenting the prescriber's determination of clinical difference.	10	25	250	30 seconds ..	2.1

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

III. Electronic Access

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

Dated: December 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31513 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–2014–D–1953]

Providing Regulatory Submissions in Electronic Format—Submission of Manufacturing Establishment Information; Draft 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 draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submission of Manufacturing Establishment Information.'' This guidance discusses the requirements for a valid electronic submission of manufacturing establishment information (MEI) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This action will streamline the review of all manufacturing establishments involved in the preparation of a drug or biological product by consolidating information in one location and eliminating the inclusion of erroneous and/or outdated information from other Agency files.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 27, 2017.

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–2014–D–1953 for ''Providing Regulatory Submissions in Electronic Format—Submission of Manufacturing Establishment Information.'' 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 the draft 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding drug products: Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4244, Silver Spring, MD 20993–0002, 301–796–3191.

Regarding biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submission of Manufacturing Establishment Information.''

This draft guidance discusses the requirements and implementation of section 745A(a) of the FD&C Act (21 U.S.C. 379k–1) regarding valid electronic submissions of MEI. Twenty-four months after this draft has been finalized, MEI contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and amendments, supplements, or resubmissions of these application types must be submitted electronically in the format specified in this guidance. This draft guidance also applies to drug master files that are submitted for incorporation by reference into an NDA, ANDA, or BLA.

Under current regulations at 21 CFR 314.50(d) and 21 CFR 601.2(a), applicants and holders of approved applications are required to submit contact information for each manufacturing establishment involved in the manufacture of the drug or biological product, as well as other information relating to the manufacture of the product. This information is part of the existing application form (FDA Form 356h, ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use''). We have found that the MEI is sometimes incomplete, and scattered throughout electronic submissions. This can lead to delays in application processing.

The Agency is requiring that applicants submit a single, consolidated list of information about each manufacturing establishment mentioned in any application. This information must include the name and address of each manufacturing establishment involved in the manufacture of the drug or biological product, specific information regarding the physical location of the establishment, facility identifiers assigned to the establishment by FDA, contact information for the person responsible for scheduling inspections at the establishment, and

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