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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:** Shabnam Naseer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, Rm. 6239, Silver Spring, MD 20993, 301-796-8539.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment."

The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of early Lyme disease as manifested by EM. Specifically, this guidance addresses FDA's current thinking regarding clinical trial design considerations such as trial populations, efficacy endpoints and clinical microbiology considerations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment." 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.

**II. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction

Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information contained in 21 CFR part 312 relating to investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 relating to new drug applications have been approved under OMB control number 0910-0001. The collections of information contained in 21 CFR part 601 relating to biologics license applications have been approved under OMB control number 0910-0338. The collections of information in 21 CFR part 201 relating to prescription product labeling requirements have been approved under OMB control number 0910-0572.

**III. Electronic Access**

Persons with access to the internet may obtain the draft 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: January 27, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-02103 Filed 1-31-23; 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 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:** Submit written comments (including recommendations) on the collection of information by March 3, 2023.

**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 0910-0354. 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](mailto: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 Processing and Importing of Fish and Fishery Products—21 CFR Part 123**

*OMB Control Number 0910-0354—Extension*

This information collection supports regulations in part 123 (21 CFR part 123), which 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 (21 CFR 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 (§ 1240.60 (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 August 2, 2022 (87 FR 47214), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section; <sup>2</sup> activity	Number of recordkeepers	Number of records per recordkeeper <sup>3</sup>	Total annual records	Average burden per recordkeeping <sup>4</sup>	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	0.30 (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	0.20 (12 minutes) .....	65,600
123.6(c)(7); Document monitoring of critical control points .....	15,000	280	4,200,000	0.30 (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	0.10 (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	0.10 (6 minutes) .....	70,500
123.11(c); Maintain sanitation control records .....	15,000	280	4,200,000	0.10 (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	0.10 (6 minutes) .....	32,800
123.12(a)(2); Prepare new written verification procedures to verify compliance of imports.	41	1	41	4 .....	164
<b>Total</b> .....					<b>1,930,264</b>

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

<sup>2</sup> 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)).

<sup>3</sup> Based on an estimated 280 working days per year.

<sup>4</sup> Estimated average time per 8-hour workday unless one-time response.

Based on a review of the information collection since our last OMB approval, we have made no adjustments to our burden estimate. 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.

Dated: January 26, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-02051 Filed 1-31-23; 8:45 am]

**BILLING CODE 4164-01-P**