

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

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA .....	356v	18	1	18	159	2,862
Phased Review with Administrative ANADA .....	356v	3	5	15	31.8	477
Biowaiver request for soluble powder oral dosage form product, using same formulation/manufacturing process approach .....	N/A	1	1	1	5	5
Biowaiver request for soluble powder oral dosage form product, using same API/solubility approach .....	N/A	5	1	5	10	50
Biowaiver request for Type A medicated article, using same formulation/manufacturing process approach .....	N/A	2	1	2	5	10
Biowaiver request for Type A medicated article, using same API/solubility approach .....	N/A	10	1	10	20	200
Total .....				51		3,604

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

We base our estimates on our records of generic drug applications. We estimate that we will receive 21 ANADA submissions per year over the next 3 years and that 3 of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated five ANADA phased review submissions and the administrative ANADA. Our estimates of the burden of biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles differ based on the type of product and the basis for the request, as shown in table 1. We estimate that an applicant will take between 5 and 20 hours to prepare a biowaiver request.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our previous estimate of the number of respondents submitting generic drug applications. However, as discussed, the burden for this information collection was increased by 265 hours and 18 responses since the last OMB approval. This is due to adding to this collection burden hours and responses for biowaiver requests.

Dated: August 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0879]

**Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with safe and sanitary processing and importing of fish and fishery products.

**DATES:** Submit either electronic or written comments on the collection of information by November 4, 2019.

**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 4, 2019. The <https://www.regulations.gov> electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of November 4, 2019. 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-2013-N-0879 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products.” 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.

- **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.gpo.gov/fdsys/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.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Procedures for the Safe and Sanitary 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 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.

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>	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> .....					1,930,264

<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 work day 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: August 26, 2019.  
**Lowell J. Schiller,**  
*Principal Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-N-3793]

**General Hospital and Personal Use Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice, establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee