

accredited issuing agencies, and consist of a specific set of characters used to identify the information immediately following the data delimiter.

For purposes of this draft guidance, we define “UDI carrier” as the means to convey the UDI and any non-UDI elements by using easily readable plain-text and AIDC forms. In the UDI carrier, the data represented in the UDI should precede any non-UDI elements and should be distinguishable from the UDI elements. The easily readable plain-text form of the UDI should be ordered to specify the DI first, followed by the PIs. If there are any non-UDI elements in the UDI carrier, the non-UDI elements should follow the PIs that are part of the UDI. For more information on non-UDI elements capable of being included in the UDI carrier, labelers should contact their FDA-accredited issuing agency.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)”. 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.

III. Request for Comments

FDA is seeking additional information on this issue. FDA is particularly interested in receiving information relating to the following question: Are there any additional standards, in addition to those referenced in this draft guidance, that should be used to determine the print quality of the AIDC form of the UDI?

IV. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm> or at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of “Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)” may send an email

request to CDRH-Guidance@fda.hhs.gov or ocod@fda.hhs.gov, or by calling 1-800-835-4709 or 240-402-7800, to receive an electronic copy of the document. Please use the document number GUD1500035 to identify the guidance you are requesting.

V. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information described in FDA regulations. These collections of information 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 collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485, and the collections of information in 21 CFR part 830 have been approved under OMB control number 0910-0720.

Dated: July 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-17554 Filed 7-25-16; 8:45 am]

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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 we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 invites comments on the information collection provisions of our regulations requiring reporting and recordkeeping for processors and importers of fish and fishery products.

DATES: Submit either electronic or written comments on the collection of information by September 26, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-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 will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://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 <http://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 <http://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.

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, PRASStaff@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

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING 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 HACCP plan (§ 123.6(a), (b), and (c)). We estimate the burden for the initial preparation of a hazard analysis and HACCP 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 HACCP 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: July 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-17571 Filed 7-25-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues (the Commission) will conduct its twenty-sixth meeting on August 31, 2016. At this meeting, the Commission will

reflect on the past, present, and future impact of national bioethics advisory bodies. Topics will include the history of national bioethics advisory bodies and their contributions to health policy, perspectives about similar bodies elsewhere, and discussion about what the future holds for groups like the Commission.

DATES: The meeting will take place August 31, 2016, from 9 a.m. to approximately 4 p.m.

ADDRESSES: Annenberg Public Policy Center, 202 S. 36th St., Philadelphia, PA 19104.

FOR FURTHER INFORMATION CONTACT: Lisa M. Lee, Executive Director, Presidential Commission for the Study of Bioethical Issues, 330 C Street SW., Suite L001, Washington, DC 20201. Telephone: 202-795-7689. Email: Lisa.Lee@bioethics.gov. Additional information may be obtained at www.bioethics.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92-463, 5 U.S.C. app. 2, notice is hereby given of the twenty-sixth meeting of the Commission. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at www.bioethics.gov.

Under authority of Executive Order 13521, dated November 24, 2009, the President established the Commission. The Commission is an expert panel of not more than 13 members who are drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences. The Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda for the Commission's twenty-sixth meeting is to reflect upon the role of national bioethics advisory bodies, both in the US and abroad, in the past, present, and future.

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful consideration of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions

during the meeting that are responsive to specific sessions. Written comments will be accepted in advance, during, and after the meeting and are especially welcome. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Written comments will be accepted by email to info@bioethics.gov, or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 330 C Street SW., Suite L001, Washington, DC 20201. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection. Time permitting, we will read aloud as many comments as possible.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 795-7689, or email at Esther.Yoo@bioethics.gov at least one week in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Dated: July 8, 2016.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2016-17620 Filed 7-25-16; 8:45 am]

BILLING CODE 4154-06-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which