

(CS), and insert the following: (3) Provides IRM policy coordination for the Center and systems contract support.

Delete items (4) and (8) from the functional statement for the *Division of Information Technology (CS34)* and insert the following: (4) Provides software consultation, database management, research, design, and support services needed by NCHS survey, registration and administrative systems, emphasizing projects which are not program specific; * * * (8) manages and administers contracts for Center-wide emerging information technology services.

Delete item (5) from the functional statement for the *Division of Information Technology (CS34)* and renumber remaining items accordingly.

Delete item (3) from the functional statement for the *Office of the Director (CS341)* and insert the following: (3) Evaluates and recommends new information technology software and methods in support of NCHS.

Delete item (2) from the functional statement for the *Office of the Director (CS341)* and renumber remaining items accordingly.

Delete items (1) and (3) from the functional statement for the *Software Solutions and Engineering Branch (CS342)* and insert the following: (1) Conducts and evaluates studies on emerging software technologies and methodologies for NCHS as input to the IT and IRM planning process and serves as a clearinghouse on these emerging technologies for NCHS; * * * (3) partners with NCHS programs, outside agencies and the States, to pilot the application of new software technologies and methodologies to meet NCHS-wide needs.

Delete in their entirety the title and functional statement for the *Network Engineering Branch (CS343)*.

Delete item (6) from the functional statement for the *Systems and Programming Branch (CS72)*, *Division of Health Interview Statistics (CS7)*, and renumber remaining items accordingly.

Delete items (3) and (6) from the functional statement for the *Informatics Branch (CS83)*, *Division of Health and Nutrition Examination Surveys (CS8)*, and insert the following: (3) develops, implements, and supports technologies, data architectures, and database management for the Division's data collection and analytic programs consistent with state-of-the-art trends in computer and informatics research; * * * (6) develops and implements standards for the Division's data collection programs and data access

(e.g., data dissemination, telemedicine applications).

Dated: November 10, 2003.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0318]

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 December 24, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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 (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (a)(4)), and became effective on December 18, 1997.

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 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 burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry.

The burden estimate in table 1 of this document includes only those

collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. For example, the current food manufacturing practices provisions in 21 CFR part 110 already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food

temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures. Furthermore, the estimate 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 of this document account only for new information collection and recording requirements attributable to part 123.

In the **Federal Register** of July 28, 2003 (68 FR 44341), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1,3}

21 CFR Section	No. of Record-keepers	Annual Frequency of Recordkeeping ¹	Total Annual Records	Hours per Record-keeper ²	Total Hours	Total Operating & Maintenance Costs
123.6(a), (b), and (c)	243	1	243	16.00	3,888	\$58,320.00
123.6(c)(5)	4,850	4	19,400	0.30	5,820	\$87,300.00
123.8(a)(1), and (c)	4,850	1	4,850	4.00	19,400	\$291,000.00
123.12(a)(2)(ii)	1,000	80	80,000	0.20	16,000	\$240,000.00
123.6(c)(7)	4,850	280	1,358,000	0.30	407,400	\$6,111,000.00
123.7(d)	1,940	4	7,760	0.10	1,940	\$29,100.00
123.8(d)	4,850	47	227,950	0.10	22,795	\$341,925.00
123.11(c)	4,850	280	1,358,000	0.10	135,800	\$2,037,000.00
123.12(c)	1,000	80	80,000	0.10	8,000	\$120,000.00
123.12(a)(2)	50	1	50	4.00	200	\$3,000.00
123.10	243	1	24	24.00	5,832	\$87,480.00
Annual Burden Hours					627,075	\$9,406,125.00

¹The above 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),(d)—Records—molluscan shellfish (see 123.6(c)(7))

Based on an estimated 280 working days per year.

²Estimated average time per 8 hour work day unless one time response

³There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0508]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 solicits comments on focus groups as used by FDA to gauge public opinion. Policymakers can use focus group results to test and refine their ideas so they can conduct further research, as well as, adopt new policies

and to allocate or redirect significant resources to support these policies.

DATES: Submit written or electronic comments on the collection of information by January 23, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers