DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Annual Survey of Refugees (ASR).

OMB No.: 0970–0033.

Description: The Refugee Act of 1980, and the Refugee Assistance amendments enacted in 1982 and 1986, stress the achievement of employment and self-sufficiency by refugees as soon as possible after their arrival in the U.S. The Annual Survey of Refugees collects information on the economic circumstances of a random sample of refugees, Amerasians, and entrants who arrived in the U.S. during the previous five years focusing on their education, training, labor force participation, and welfare utilization rates. From their responses, ORR reports on the economic adjustment of refugees to the American economy. These data are used by Congress in its annual deliberations of refugee admissions and funding and by program managers in formulating policies for the future direction of the Refugee Resettlement Program.

Respondents: Approximately 2,000 refugees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondents	Average burden hours per response	Total burden hours
ASR Telephone Survey	2,000	1	40 minutes	1,350
Estimated Total Annual Burden Hours:				1,350

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: October 11, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–26657 Filed 10–16–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1379]

Agency Information Collection Activities; Submission for OMB 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 the proposed collection of information listed below 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 on the collection of information by November 16, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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 Processing and Importing of Fish and Fishery Products (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 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 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 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 good 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 account only for new information collection and recording requirements attributable to part 123.

In the **Federal Register** of July 21, 2000 (65 FR 45382), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping[2]	Total Annual Records	Hours per Recordkeeper[3]	Total Hours	Total Operating and Maintenance Costs
123.6(a), (b), and (c)	243	1	243	16	3,888	$58,320
123.6(c)(5)	4,850	4	19,400	0.30	5,820	$87,300
123.8(a)(1) and (c)	4,850	1	4,850	4	19,400	$291,000
123.12(a)(2)(ii)	1,000	80	80,000	0.20	16,000	$240,000
123.6(c)(7)	4,850	280	1,358,000	0.30	407,400	$6,111,000
123.7(d)	1,940	4	7,760	0.10	1,940	$29,100
123.8(d)	4,850	47	227,950	0.10	227,795	$341,925
123.11(c)	4,850	280	1,358,000	0.10	135,800	$2,037,000
123.12(c)	1,000	80	80,000	0.10	8,000	$120,000
123.12(a)(2)	50	1	50	4	200	$3,000
123.10	243	1	24	24	5,832	$87,480
Total					627,075	$9,406,125

[1] There are no capital costs associated with this collection of information.
[2] Based on an estimated 280 working days per year.
[3] Estimated average time per 8-hour work day unless one time response.
The 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)), and
§ 123.28(c), (d) Records—molluscan shellfish (see § 123.6(c)(7)).

Dated: October 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–26607 Filed 10–16–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 15 and 16, 2000, from 8:30 a.m. to 5:30 p.m.

Location: University of Maryland, Shady Grove Campus, Auditorium, 9640 Gudelsky Dr., Rockville, MD 20850.

Contact Person: Nancy Chamberlin, Center for Drug Evaluation and Research (HFD 21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: CHAMBERLINN@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 15, 2000, the committee will: (1) Discuss approaches to reducing the regulatory burden for chemistry, manufacturing, and controls supplements; and (2) hear reports and provide direction to the Advisory Committee for Pharmaceutical Science's Subcommittee on Orally Inhaled and Nasal Drug Products, and to the Subcommittee on Nonclinical Studies. On November 16, 2000, the committee will: (1) Discuss the FDA guidance entitled ''A Guidance for Industry, Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System,'' see the FDA Internet web address www.fda.gov/cder/guidance/3618fnl.htm under the heading of ''Biopharmaceutic Guidances;'' the FDA draft guidance entitled ''A Guidance for Industry, BA and BE Studies for Orally Administered Drug Products-General Considerations,'' see the FDA Internet