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]

BILLING CODE 4160–01–F

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

web address www.fda.gov/cder/guidance/2762dft.htm under the heading of ''Biopharmaceutic Draft Guidances;'' and the FDA draft guidance entitled ''A Guidance for Industry, Average, Population, and Individual Approaches to Establishing Bioequivalence,'' see the FDA Internet web address www.fda.gov/cder/guidance/1716dft.htm under the heading of ''Biopharmaceutic Draft Guidances;'' (2) provide comments and advice to the Clinical Pharmacology Modeling and Simulation Working Group; (3) receive updates on both FDA intramural research and the Product Quality Research Institute; and (4) provide advice on scientific issues specific to generic drugs.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 5, 2000.

Bernard A. Schwetz,

Acting Deputy Commissioner.

[FR Doc. 00–26606 Filed 10–16–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Survey of IRB Chairs Concerning the Implementation of Pediatric Research Regulations

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Survey of IRB Chairs Concerning the Implementation of Pediatric Research Regulations.

Type of Information Collection Request: New.

Need and Use of Information Collection: In order to assess the protection of children who are enrolled in clinical research, it is important to determine how Institutional Review Boards (IRBs) reviewing such research interpret and implement the Federal Regulations for research with children set forth in 45 CFR 46 Subpart D. This study aims to gather this information through telephone interviews with chairpersons of IRBs that review clinical research with children. In addition, we will solicit background information on each IRB from the IRB coordinator. In particular, the survey aims to assess how IRBs assess risk/benefit levels of research with children, when IRBs permit children's assent to be waived, what information IRBs require children to be presented during the asset process, and which children are excluded from participation in riskier research. In addition, the survey will attempt to determine how the recent NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects has affected IRB review. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* IRB chairpersons and IRB coordinators. The annual reporting burden follows in the table below. The annualized cost to respondents is estimated at: $10,000. There are no Capital Costs to report. There are no Operating or Maintenance Cost to report.

RESPONDENT AND BURDEN ESTIMATE INFORMATION

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
IRB chairs	200	1	0.5	100
IRB coordinators	200	1	0.5	100
Total	.....	.....	.....	200

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dave Wendler, Ph.D., Head, Unit on Vulnerable Populations, Department of Clinical Bioethics, NIH, Building 10, Room 1C118, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435–8726 or e-mail your request, including your address, to: DWendler@cc.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before December 18, 2000.

Dated: October 4, 2000.

Ezekiel Emanuel,

Chief, Department of Clinical Bioethics.

[FR Doc. 00–26581 Filed 10–16–00; 8:45 am]

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