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 Recordkeepers	Annual Frequency of Recordkeeping[1]	Total Annual Records	Hours per Recordkeeper[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

[1]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))
§ 123.28(c),(d)–Records—molluscan shellfish (see 123.6(c)(7))
Based on an estimated 280 working days per year.
[2] Estimated average time per 8 hour work day unless one time response
[3] There 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.

[FR Doc. 03–29195 Filed 11–21–03; 8:45 am]

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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

Lane, Rockville, MD 20857, 301–827–4659.

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.

Focus Groups as Used by the Food and Drug Administration—(OMB Control Number 0910–0497)

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more indepth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

FDA estimates the burden for completing the forms for this collection of information in table 1 of this document .

The total annual estimated burden imposed by this collection of information is 2,830 hours annually.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication	10	100	9	1.58	1,422
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, consumer education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (e.g., animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468
Total		28	186		1.78	2,830

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

Annually, FDA projects about 28 focus group studies using 186 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29197 Filed 11–21–03; 8:45 am]

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