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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00N-0356]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Incidence of Gastroenterological Parasitic Infections in the United States as a Result of Consumption of Raw Fish**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary survey about the incidence of gastroenterological parasitic infections in the United States as a result of the consumption of raw fish.

**DATES:** Submit written comments on the collection of information by *[60 days after publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (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:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Room 16B-26; Rockville, MD 20857, 301-827-1223.

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**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 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: (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.

**Title: Survey of Incidence of Gastroenterological Parasitic Infections in the United States as a Result of Consumption of Raw Fish**

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)), the FDA has the responsibility to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation’s food supply. The “Survey of Incidence of Gastroenterological Parasitic Infections in the United States as Result of Consumption of Raw Fish” will provide information on the actual frequency of occurrence of fish-borne helminth illnesses. Detailed information will be obtained from the target population of clinical gastroenterologists who are likely to have encountered and treated food-borne parasitic

infections. Respondents will also be asked to provide demographic information about the most recent cases. The information will be used to better evaluate the need for control of helminth parasites in fish intended for raw consumption and to evaluate effective means for control where such controls are found necessary. A national representative sample of 1,000 clinical gastroenterologists will be selected by a random procedure and interviewed by questionnaire.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
500	1	500	.50	250

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This is a one time survey. The burden estimate is based on FDA's experience with conducting similar surveys.

Dated: February 14, 2000



William K. Hubbard  
 Senior Associate Commissioner  
 for Policy, Planning, and Legislation

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