

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0356]

Agency Information Collection Activities; Submission for OMB Review; 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.

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 *[insert date 30 days after date of publication in the Federal Register]*.

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.

DMB

Application Date	5-22-00
Publication Date	5-23-00
Certifier	W. Pease

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(b)(2)), 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 a 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.

In the **Federal Register** of February 22, 2000 (65 FR 8713), the agency requested comments on the proposed collections of information. One comment was received. The comment commended the concept of conducting the survey, but requested that the survey gather information sufficient to determine whether implicated fish were from commercial or recreational sources.

The comment's point is that because the purpose of the survey is to help determine whether infection from fish-borne helminth parasites is a hazard that is responsibly likely to occur in the United States in commercial species of fish, data on parasite infections from noncommercial species could skew the outcome. While the comment's point is valid in theory, it is highly unlikely that recreational species are a significant source of parasite infections. It is more likely that commercial species intended for raw consumption, as in sushi and sashimi, provide an appreciable risk of parasite infection. Consequently, the agency does not regard differentiation between commercial and recreational sources to be critical to the success of the survey. As a practical matter, moreover,

information on whether an infection was from a commercially or recreationally obtained fish is probably not available through the kind of survey that is being conducted. Consequently, FDA does not contemplate any change in the survey.

Any findings of significant levels of infection will guide FDA in evaluating its current policy that fish intended for raw consumption should have been previously frozen to eliminate the hazard from live parasites. This recommendation is adhered to by many members of the seafood industry. To the extent that parasite infection from raw fish is demonstrated through this survey to be a hazard reasonably likely to occur, the agency would focus its attention to such actions as increased consumer education, which would apply to raw fish from any source, and to ensuring the implementation of hazard analysis critical control points for fish sold for raw consumption.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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

¹There 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: May 15, 2000



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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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