Information Collection Request Supporting Statement

for

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

INFORMATION COLLECTION REQUEST SUPPORTING STATEMENT

0910-0443

The purpose of this supporting statement is to verify that the collection of information encompassed by this request complies with the Paperwork Reduction Act of 1995. The supporting statement shows that this information collection is necessary to determine the incidence of gastroenterological parasitic infections in the United States as a result of consumption of raw fish. FDA has concluded that helminth parasites pose a health hazard to consumers of raw fish, despite the lack of formally reported and recorded data. In order to resolve this issue, more complete data are needed on the actual frequency of occurrence of fish-borne helminth illnesses in the U.S.

A mailed questionnaire survey approach will be used for data collection. A sample of 1000 members of the American Gastroenterologist Association (AGA) will be selected using random sampling. The sample allocation is designed to yield 500 completed surveys from member gastroenterologists practicing in states bordering the Atlantic and Pacific Oceans and the Gulf of Mexico. The purposes of this information collection are to (1) ascertain the incidences of gastroenterological helminthic infections respondents have diagnosed, treated, or referred and (2) help the agency better evaluate the need for control of helminth parasites in fish intended for raw consumption and to evaluate effective means for control where controls are found necessary. The survey data will be used to determine the actual frequency of occurrence of fish-borne helminth illnesses. Respondents will be asked to provide demographic information about the most recent cases.

Upon OMB approval, a mailed questionnaire survey approach will be used by AGA to collect the data. In Phase 1, the AGA will send out an advanced notice postcard to member gastroenterologists. Four days following the advanced notice, AGA will send out a cover letter, questionnaire, and stamped, self-addressed envelope requesting that gastroenterologists provide information about incidences of gastroenterological helminth infections they have diagnosed, treated, or referred. The AGA will provide a financial incentive ($15) for respondents. In Phase 2, AGA will send out a second letter, questionnaire, and stamped self-addressed envelope to gastroenterologists who have not responded within (4) weeks of the first mailing. One week later, AGA will send out a reminder/thank you postcard. In Phase 3, AGA will send out a final reminder letter and replacement form to those who do not return the mail survey in the specified timeframe.

As required by the Office of Management and Budget, Section A of this supporting statement provides a justification for this information collection, while Section B provides information about the statistical methods employed by this information collection. As required, Appendix 1 contains the text of a notice to the public published in the *Federal Register*. Appendix 2 contains the advance notice postcard and cover letter. Appendix 3 contains the mail survey instrument. Appendix 4 contains the reminder/thank you and final reminder letter.

A. JUSTIFICATION

A.1 Circumstances

The Federal Food, Drug, and Cosmetic Act (the Act), section 402 (a) (1), 21 U.S.C. 342 (a) (1), deems food to be adulterated under certain circumstances if it contains any poisonous or deleterious substances. The primary purpose of this survey is to learn when fish and fishery products that are likely to be consumed raw are reasonably likely to contain harmful parasites and thus be adulterated under section 402 (a) (1). In obtaining this information, FDA is condulting research in accordance with section 903 of the Act (21 U.S.C. 393 (b) (2) (c), to enable it to carry out its responsibilities for food. The agency has established a policy requiring the freezing of finfish as the means to control helminth parasites in fish intended for raw consumption. On August 21, 1987, FDA issued interpretation 2-403 for the Food Code, which specified requirements for freezing fish. This was done in order to provide public health control for fish borne helminth parasites (Food Code, 3-402.11). The Fish and Fisheries Products Hazards and Controls Guide, which provides guidance to seafood producers developing Hazard Analysis and Critical Control Point (HACCP) plans and to regulators conducting inspections of seafood processors, includes freezing as the recommended control for parasites in fish intended for raw consumption. Many members of the seafood industry and some state public health regulators disagree that parasites in raw fish pose a significant hazard. Some industry members have stated that they do not intend to adopt freezing as a means of control, nor do they believe control is necessary.

The FDA has issued Task Order #1:"Survey of Incidence of Gastroenterological Parasitic Infections in the United States as a Result of Consumption of Raw Fish" to obtain the information needed to better evaluate the need for controls and to evaluate effective means for

controls where such controls are found necessary. FDA has concluded that helminth parasites pose a health hazard to consumers of raw fish, despite the lack of formally reported and recorded data. In order to resolve this disagreement, more complete data are needed on the actual frequency of occurrence of fish borne helminth illnesses in the U.S.

Infections from parasitic "worms," loosely referred to as helminths, pose a major health hazard to humans. These parasites include the Nematoda (round worms), Cestoda (tape worms), Trematoda (flat worms), and less common forms. Some of these parasites are transmissible to man through the ingestion of raw or undercooked food. Raw seafood includes forms such as marinades (e.g., ceviche, pickled herring) and cold smoked fish in addition to sushi and sashimi forms.

The nematodes, particularly members of the anisakid group, pose a particular concern for persons eating raw marine fish. Other helminths are also transmitted through the consumption of raw fish, but because fish used in the US for raw consumption are usually marine/estuarine fish, the largest hazard appears to be from infection by members of the anisakid group.

The first cases of human illness (11 cases that occurred from 1955 to 1959 in Dutch consumers of green herring) caused by a roundworm from fish, were reported in 1960. In 1964 the organism that caused the disease was reclassified as a member of the genus *Anisakis* where it remains today. In 1967, 47 cases were reported in Holland. In response, Holland passed legislation, which required the freezing of fish used for green herring. In 1968, the number of cases in Holland dropped to five and in subsequent years only cases where the infection was acquired overseas have been reported. Soon after this FDA decided that this emerging pathogen warranted agency attention and in 1972 established a parasitology laboratory to study the potential for food borne parasites to cause illnesses in US consumers. Coincidentally this was the year the first North American cases of anisakiasis were reported.

Research conducted by FDA and others have demonstrated anisakid larvae in the edible portions of a wide variety of fishes. Anisakis larvae have been reported from the roe of salmon. Salmon and cod have the greatest anisakid burden in the flesh of any other fish reported. In

addition to infections with roundworms, human infections with flatworms and acanthocephala from fish have been reported in the U. S.

Many physicians who are aware of the disease treat it as routine and do not publish cases. Seafood borne parasitic diseases are not required to be reported by any of the states and therefore go largely ignored. An anecdotal piece of evidence supports FDA's belief that there are in actuality a substantial number of cases in the US. Approximately ten years ago, a news agency interested in doing a story on the potential hazards of raw fish consumption, phoned the first 5 gastroenterologists in the Washington DC phone book. The news agency reported to FDA that 3 of the gastroenterologists said that they had treated a total of 5 patients for anasakid infection during the past year. Other than this report there have been no attempts to determine the actual incidence of parasitic infections from the consumption of raw fish.

A.2 Use of Information

The Office of Seafood of the Center for Food Safety and Applied Nutrition will primarily use the information gathered in the study. The purposes of this information collection are to (1) ascertain the incidences of gastroenterological helminthic infections respondents have diagnosed, treated, or referred and (2) help the agency better evaluate the need for control of helminth parasites in fish intended for raw consumption and to evaluate effective means for control where controls are found necessary. The survey is organized to determine the actual frequency of occurrence of fish-borne helminth illnesses. Respondents will be asked to provide demographic information about the most recent cases.

A.3 Use of Information Technology

Information about the actual frequency of occurrence of fish borne helminth illnesses in consumers of raw fish is not known, and such information will enable FDA to better evaluate the need and effective means for controls. The information will be incorporated into the next edition of the FDA Fish and Fisheries Products Hazards and Controls Guide, which is available in hard copy and on the FDA website.

A.4 Duplication Identification

A search of published literature and FDA archives by the Office of Seafood, Division of Science and Applied Technology of the Center for Food Safety and Applied Nutrition failed to identify any data that statistically estimate the frequency of occurrence of fish-borne helminth illnesses in the U.S.

A.5 Minimize Burden to Small Entities

Because the survey will be administered to a sample of gastroenterologists representative of the subpopulations of interest, small entities will certainly be respondents. However, FDA does not feel that alternative collection procedures for small entities are necessary. The entities will not be required to collect or record information, since their survey responses will be derived from their standard procedures and existing records. Also, because a mail survey is being used, the survey can be completed at the convenience of respondents.

A.6 Consequences of Not Conducting Collection

FDA will collect data only once to conduct a statistical analysis to determine frequency of occurrence of fish-borne helminth illnesses in consumers of raw fish. Without this data collection, the actual frequency of occurrence of fish borne helminth illnesses in consumers of raw fish is not known, and the information needed to better evaluate the need for controls and to evaluate effective means for controls will not be obtainable.

A.7 Special Circumstances Explanation

No special circumstances require additional explanations.

A.8 Public Comments and Consultation Outside the Agency

In the Federal Register of Tuesday, February 22, 2000 (65 FR 8713), FDA requested comments on the information collection from the public. No significant comments were received.

A.9 Payment or Gift to Respondents

No payment or gift to respondents will be included.

A.10 Assurance of Confidentiality

The confidentiality of respondents will be assured by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. FDA will not have access to the survey responses of individual gastroenterologists. The American Gastroenterological Association, LSRO's subcontractor will develop the sampling frame, draw the sample, contact the participants, collect the data, and record and analyze the data.

AGA has standard procedures for assuring the confidentiality of survey respondents. AGA manages the data collected from human subjects in ways that prevent unauthorized access at any point during the study. AGA's confidentiality guidelines specifically restrict the release of personally identifying information about respondents to anyone outside the project team. These procedures improve the response rate and ensure the confidentiality of all interview data.

AGA will not disclose the responses of individual gastroenterologists . AGA will only report survey results in aggregate, pooling the responses from gastroenterologists within a stratum. No survey results will be reported for strata with fewer than ten observations.

A.11 Sensitive Sexual, Religious, or Private Information

Questions of a sensitive nature are not applicable to this information collection.

A.12 Hour Burden Estimates

FDA estimates that the burden of this collection of information will average .50 hours per respondent (see Table 1). This estimate covers the entire survey process, including making the initial mailed contact and completing the survey by mail.

Table 1. Estimated Annual Reporting Burden[a]

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
500	1	500	.50	250

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

A.13 Total Annual Cost Burden to Respondents or Recordkeepers Excluding Hours Burden Shown in Items 12 and 14

Not applicable. Respondents will have no additional burden beyond the hour's burden shown in item A.12. Respondents will not need capital equipment, ongoing recordkeeping operations, or services to complete the information collection.

A.14 Annual Cost to the Federal Government

LSRO estimates the total cost to the Federal Government for this information collection to be $39,354 which represents 160 labor hours and incidental costs such as mailing, communications, and supplies. As shown in Table 2, this estimate includes AGA's activities, as well as LSRO's. AGA and FDA will work jointly refining the survey instruments, reviewing sampling design and data collection methods. AGA will develop and pretest the survey instrument, design and draw the sample, collect the data, analyze the data, and produce a final report.

Table 2. Agency and Contractor Annual Burden/Cost Estimates

	Burden Hours						
Contractor Service (LSRO)	Management	Technical	Clerical	Total Hours	Cost	Other Costs	Total Cost
Director	20			20	$ 1,026		$ 1,026
Administrator	50			50	$ 1,187		$ 1,187
Fringe Benefits @ 25%					$ 553		$ 553
Other Direct Costs					$ 335		$ 335
Indirect Costs					$10,125		$10,125
Fixed Fee					$ 2,228		$ 2,228
Subcontractor (AGA)							
Develop Survey Instrument	24			24	$3,600	10	$3,610
Pretest Survey Instrument	4	4	2	10	$970	10	$980
Design and Draw Sample	4	4	4	12	$1,040	100	$1,140
Conduct survey mailings	4	12	24	40	$2,340	2485	$4,825
Data entry		3	24	27	$1,065	10	$1,075
Analyze Data	40			40	$6,000	100	$6,100
Produce Final Report	40		2	42	$6,070	100	$6,170
Total Burden and Cost	186	23	56	265[1]	$36,539	2815	$39,354

[1]This total includes 250 hours of estimated annual reporting burden and 15 hours of agency burden.

A.15 Explanation of Program Changes or Adjustments

This is a new collection.

A.16 Publication of Results

AGA will use the data to prepare a report that discusses the incidence and demographic characteristics of fish-borne helminth parasitic infection in the coastal areas of the United States. Tables 3 and 6 show how AGA will organize this information.

Table 3. Description of Population, Sample and Response

Coastal Area	No./% of AGA Members	Sample (#/%)	Response (#/%)
Atlantic	2,110/62.0%		
Gulf	599/17.6%		
Pacific	694/20.4%		
Totals	3,403/100.0%		

Table 4. Number and Percentage of Physicians Reporting Cases of Helminth Infection

Coast	No./% of Response	Projected to Sample (No.)	Projected to AGA Membership (No.)
Atlantic			
Gulf			
Pacific			
Totals			

Table 5. Number of Cases from the Physicians Who Responded "YES"

Infection	No./% of Response	Projected to Sample (No.)	Projected to AGA Membership (No.)
Anisikiasis			
Diphyllobothriasis			
Pseudoterranoviasis			
Totals			

Table 6. Case Demographics

Characteristic	No. of Cases/% of Total Cases
Ethnicity	
American Indian or Alaskan Native	
Asian	
Black or African-American	
Hispanic or Latino	
Native Hawaiian or Other Pacific Islander	
White	
Gender	
Male	
Female	
Age	
<20	

20-29	
30-39	
40-49	
50-59	
60-69	
≥70	

This voluntary survey is a one-time collection of information to determine the incidence of gastroenterological parasitic infections in the United States as a result of the consumption of raw fish. Target dates are listed in Table 7.

A.17 Explanation of Inappropriateness of Displaying OMB Approval Expiration Date

No exemption is requested.

A.18 Exceptions to the Certification Statement of OMB Form 83.I

No exceptions requested.

Table 7. Survey Schedule

Activity	Start Date	End Date
OMB approval	05/15/00	06/23/00
Pretest of Survey Questionnaire	07/03/00	07/17/00
Data collection	07/17/00	08/21/00
Data analysis	08/21/00	08/28/00
Final report production	08/28/00	09/04/00

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Describe Universe

The universe to be surveyed is the approximately 3,400 AGA clinician members in the coastal states (including AK and HI). A 25% single simple random sample will be drawn. See table 1. Note that obtaining data from physicians' office records is difficult and so a response rate of 80% is expected.

B.2 Procedures

A mail survey will be conducted. Survey mailings will consist of an advance notice postcard, survey questionnaire and cover letter with postage paid reply envelope, reminder/thank you postcard, and a reminder mailing consisting of a cover letter and replacement questionnaire.

B.3 Methods to Maximize Response Rate

Procedures to maximize the response rate include cover letters signed by the AGA president, advance notice to recipients, and two reminder mailings (postcard and replacement questionnaire mailing). All mailings will be by 1st class mail.

B.4 Tests of Procedures and Methods

If desired by FDA a pretest of the survey questionnaire will be conducted among 8 names drawn from the sample. This pretest will delay finalization of the questionnaire by approximately three weeks.

B.5 Statistical Consultant's Name and Telephone Number and Data Collection

The contact person for the survey:

Michael Stolar, Ph.D
American Gastroenterological Aassociation
7910 Woodmont Avenue, 7th Floor
Bethesda, MD 20814-3015

Tel: 301.654.2055, ext. 608
Fax: 301.654.5920

REFERENCE

Federal Register. February 22, 2000. "Survey of the Incidence of Gastroenterological Parasitic Infections in the United States as a Result of the Consumption of Raw Fish." Vol. 65, No. 35.

APPENDIX 1

FEDERAL REGISTER NOTICE

APPENDIX 2

ADVANCE LETTER

APPENDIX 3

COVER LETTER AND MAIL SURVEY INSTRUMENT

APPENDIX 4
REMINDER/THANK YOU AND FINAL REMINDER LETTER