Survey to **Investigate Awareness of the Mississippi Delta Fish Advisory and the Relationship between the Advisory and Related Fishing Behaviors**

0910-NEW

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), the Food and Drug Administration (FDA) is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. In June 2005, the Environmental Protection Agency's (EPA) Office of Water and FDA's Center for Food Safety and Applied Nutrition finalized a Memorandum of Understanding (MOU) to enhance collaboration between FDA and EPA regarding environmental contaminants in fish and shellfish and the safety of fish and shellfish for U.S. consumers. The MOU is available at http://www.epa.gov/waterscience/fish/files/moufdaepa.pdf. The proposed survey will gather information about fishing and fish consumption habits in the Mississippi Delta region, as well as the respondents' awareness and understanding of the Regional Delta Advisory (RDA) issued by the Mississippi Department of Environmental Quality (MDEQ).

The proposed is phase two of a two phase study designed to determine whether existing fish consumption recommendations issued by the state of Mississippi are adequately protecting sport and subsistence consumers of fish harvested from Delta waters. The final report of phase one, entitled "Recommended Study Design for a Survey to Evaluate the Effectiveness of Mississippi Delta Fish Advisories," is available at http://www.epa.gov/waterscience/fish/technical/ms-delta.html. Based on this report, FDA is conducting the proposed survey on behalf of EPA to investigate the prevalence of awareness of the advisory and whether the advisory is associated with any reported changes in fishing and consumption behaviors.

2. Purpose and Use of the Information Collection

The information collection includes in-person, on-the-bank interviews with anglers and an in-person household survey in four counties located in the advisory area. Both population groups will be asked to respond to the same questionnaire. The questionnaire was developed by a workgroup with expertise in survey research, sociology, fish consumption advisories, and the Mississippi Delta culture. FDA will contract with RTI

International (RTI) to conduct the study. RTI plans to subcontract with Delta State University, a university located in the Mississippi Delta, to conduct the on-the-bank and household interviews.

The proposed survey will collect information on the extent to which Delta sport and subsistence fishermen and their families are aware of the RDA and its recommendations and the extent to which the respondents report changing their fish consumption behaviors as a result of the advisory. The survey will also document specific behavior changes after hearing of the RDA, such as increases or decreases in the amount of locally harvested fish consumed, changes in methods of fish preparation, and consumption or avoidance of specific species of fish. Results of the survey will provide FDA and EPA information about fishing and fish consumption habits in the Mississippi Delta region, as well as the respondents' awareness and understanding of the RDA.

FDA and EPA understand that this is a retrospective study of reported fishing and fish consumption changes, which may or may not be result of awareness of the Regional Delta Advisory. To evaluate the effectiveness of the advisory, one would need a pre-post study of the behaviors in question. However, there are no data available about fishing practices in the Mississippi Delta prior to the advisory. In addition, a retrospective study relies on respondents' self reported changes in fish consumption and fishing practices, which are vulnerable to errors and biases and may cast doubts on the causal relationships between the advisory and its behavioral effects. Nevertheless, we believe that this study will provide FDA and EPA useful information about consumer awareness of the advisory and about their self reported changes in fishing behavior and fish consumption.

3. Use of Improved Information Technology and Burden Reduction

The proposed data collection effort will involve in-person interviews. Survey responses will be recorded with pen and paper; thus, information technology resources will not be used to collect data. Because of the small sample size of the survey (1,000 interviews), it would not be cost-effective to develop a computerized system (e.g., computer-assisted personal interviewing [CAPI]) for the data collection.

4. Efforts to Identify Duplication and Use of Similar Information

FDA and its contractor, RTI, have thoroughly researched the availability of accurate, quantitative data that describe consumers' awareness and response to the RDA implemented by MDEQ. No existing sources were found. No comparable data have been collected by any other means.

5. Impact on Small Businesses or Other Small Entities

No small businesses would be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The proposed survey is a one time collection. No successive related data collections are planned. If this information is not collected, FDA and EPA will have no knowledge about the effectiveness of the RDA implemented by MDEQ. Lack of this information would negatively impact EPA and MDEQ's educational and public information programs relating to the safe consumption of fish from the Mississippi Delta region.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus 2 copies of the information; or, retain records for more than 3 years. The design of the statistical survey will not produce results that cannot be generalized to the universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of, October 24, 2008 (73 FR 63487), FDA published a 60-day notice requesting public comment on the proposed information collection. The agency did not receive any comments during the 60-day comment period.

In 2007, FDA and EPA convened a workgroup to develop the survey instrument, sample design, and survey approach for the study. The workgroup comprised individuals from academia, EPA, FDA, and MDEQ, as well as individuals representing Mississippi Delta communities and the contractor. Workgroup members included:

- Ralph Brown, Brigham Young University;
- Joanne Burger, Rutgers State University;
- Joan Wesley, Jackson State University;
- Pat Cunningham, RTI;
- Jeffrey Bigler, EPA;
- William Gross, EPA;

- Steven Bradbard, FDA;
- Steve Goff, MDEQ;
- Henry Folmer, MDEQ;
- Glen Donald, community leader in the Mississippi Delta;
- Gary Lucas, Mississippi Department of Wildlife and Fisheries; and
- Barbara Brooks, Mayor of Leland, Mississippi.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be made to respondents.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The survey questionnaire and screener contain a statement that responses will be kept confidential. Confidential information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

Prior to starting data collection, FDA's Institutional Review Board (IRB) will review the survey protocol to ensure that human subjects are protected and that confidentiality procedures are adequate. An independent contractor for FDA, RTI, and their subcontractor, Delta State University, will collect the data and will not provide FDA with identifying information on the respondents. Respondents will be promised that their data will be treated as confidential and released to the public only in the form of aggregate statistics that cannot be associated with any individual or household. Interviewing staff are required to sign a pledge of confidentiality that reinforces confidentiality requirements of the study and states that any procedural violation that jeopardizes a respondent's privacy will be grounds for immediate termination and possible legal action. Once response editing and interview validation are completed for the survey data, respondents' names and other identifying information will be permanently dissociated from interview data.

All data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The survey instrument does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The respondents are adults, age 18 and older, who fish or eat fish caught in the waters covered by the RDA.

The total estimated burden imposed by this collection of information is 316 hours. Table A.1 provides summary estimates of respondent burden.

Table A.1 Estimated Annual Reporting Burden[1]

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive Interviews	6	1	6	1.0	6
Pretest	20	1	20	0.5	10
Survey	1,000	1	1,000	0.3	300
Total					316

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

The respondents will be selected from four counties in the Mississippi Delta region. Counties were selected to include a mix of rural and non-rural areas and areas with major water resources affected by the advisory. The selected counties are Coahoma, Holmes, Leflore, and Washington. Only the part of Holmes County that is within the advisory area will be included in the survey. The total sample will include 400 on-the-banks interviews and 600 household interviews of sport and subsistence fishers who harvest noncommercial fish from the Mississippi Delta advisory area, and individuals in the Mississippi Delta area who consume wild-caught fish from the advisory area. FDA estimates that the survey will take approximately 18 minutes to complete, for a total burden of 300 hours (1,000 x 0.3 = 300). FDA will conduct 6 cognitive interviews and 20 pretests prior to fielding the survey, for a total additional burden of 16 hours. FDA's burden estimate is based on the agency's prior experience with surveys similar to the proposed survey.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The estimated cost to the federal government is $200,000. This cost includes costs paid to the contractor to draw the sample, collect the survey data, create a database of the data,

tabulate and summarize the survey data, and prepare a final report. This cost also includes FDA and EPA staff time to manage the study.

15. Explanation for Program Changes or Adjustments

This is a new data collection. The new burden hours are due to a one-time survey and its related cognitive interviews, pre-test, and screener.

16. Plans for Tabulation and Publication and Project Time Schedule

The 1,000 completed interviews will include two groups: (1) 400 on-the-bank interviews and (2) 600 household interviews. Table A.2 outlines the time frame for data collection and analysis.

Activities associated with the outcomes of this research will primarily consist of a written final report. Data in the report will primarily be descriptive. Additionally, cross-tabulations will look at the relationship between demographic variables such as education, race/ethnicity, age, and gender, and awareness of the advisory to see if there are any particular segments of the MS Delta population that are more or less aware of the advisory. Cross-tabulations will also look at the relationship between demographic variables and changes made in fishing practices and in fish consumption. Finally, we hope to explore relationships between following the advisory recommendations and awareness of the advisory, perceptions of the importance of following the advisory recommendations, and demographic variables,

Table A.2 Project Schedule

Date	Activity
Within 1 day after receipt of OMB approval of collection of information	Notification to contractor to proceed with data collection activities
Within 120 days after receipt of OMB approval of collection of information	Completion of data collection and delivery of data by contractor
Within 60 days after completion of data collection	Completion of preliminary analyses
Within 60 days after completion of preliminary analyses	Completion of final analyses and report

17. Reason(s) Display of OMB Expiration Number is Inappropriate

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions requested.