

# **FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)**

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Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

**TITLE OF INFORMATION COLLECTION:** Fish Consumption Focus Groups

## **DESCRIPTION OF THIS SPECIFIC COLLECTION**

### **1. Statement of need:**

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)/Office Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group study, “Fish Consumption Focus Groups,” to collect qualitative information about how certain consumers may currently understand existing dietary recommendations related to fish consumption and methylmercury in fish. The purpose of this focus group study is to explore participants’ knowledge, perceptions, and beliefs that could help inform the agency’s thinking about potential future updates to the 2004 FDA/EPA consumer advisory on methylmercury in fish.

### **2. Intended use of information:**

Fish is a nutrient-rich food, low in saturated fat and high in protein and omega-3 fatty acids. Research has suggested that fish consumption may be linked to reduced risk of certain forms of heart disease and that maternal fish consumption during pregnancy may be beneficial to fetal neurodevelopment. However, some fish can also contain high levels of methylmercury, which has been linked to adverse health effects, especially on the cognitive development of fetuses. Fish consumption is the primary way Americans are exposed to methylmercury.

In 2004, the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) issued joint advice about mercury in fish. The 2004 advice provided the following 3 recommendations for pregnant women, women who might become pregnant, nursing mothers and young children: “1) Do not eat shark, swordfish, king mackerel, or tilefish because they contain high levels of mercury; 2) Eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury. Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, pollock, and catfish. Another commonly eaten fish, albacore (“white”) tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to 6 ounces (1 average meal) of albacore tuna per week; and 3) Check local advisories about the safety of fish caught by family and friends in your local lakes, rivers, and coastal areas. If no advice is available, eat up to 6 ounces (1 average meal) per week of fish you catch from local waters, but don’t consume any other fish during that week”.

Recent evidence has suggested that pregnant women may not be eating enough fish to get all of the potential benefits that fish could provide to fetal neurodevelopment. The 2010 Dietary Guidelines for Americans states that, “In addition to the benefits for the general public, the nutritional value of seafood is of particular importance during fetal growth and development, as well as in early infancy and childhood...Therefore, it is recommended that women who are pregnant or breastfeeding consume at least 8 and up to 12 ounces of a variety of seafood

per week, from choices that are lower in methyl mercury.” Therefore, FDA and EPA are interested in understanding how pregnant women and women who may become pregnant understand the fish consumption advice from the 2010 Dietary Guidelines for Americans.

FDA plans to use the study to explore consumers’ understanding of the benefits and risks of fish consumption. The agency will use the knowledge as an input to explore possible ways to make FDA/EPA advisory about fish consumption more consumer-friendly and consistent with the 2010 Dietary Guidelines for Americans.

**3. Description of respondents:**

A total of 12 focus groups are planned. Nine of the groups will be with women who are either pregnant or who have a child/children less than five years old. The other three groups will be with women ages 18 to 45 who have never been pregnant and don’t have children under the age of five but who are considering becoming pregnant in the next few years. All women will have eaten fish, at least once, in the past year. Half of the groups will be with women with some college or higher levels of education and half with women who have lower levels of education. Within these groups there will be a mix of ages and races/ethnicities. We will recruit 12 women for each group, and expect to have 8 to 10 participants per group. No more than 12 participants will participate in a group. (See Appendix I)

**4. Date(s) to be conducted and location(s):**

Focus groups will be conducted approximately one month from the date of OMB approval. The focus groups will be conducted in six locations: Washington, DC (metro area), Northeast, Gulf region, the Mid-West (inland), the Great Lakes region, and the West Coast.

**5. How the Information is being collected:**

With the aid of a moderator’s guide (see Appendix II), a moderator supplied by the independent contractor will guide the focus group discussions that will solicit information from the participants. The focus group discussion will be recorded and transcripts will be made from these recordings. Transcripts and notes taken by the project staff will be the bases for data analysis. Transcripts and notes will be used to analyze data.

**6. Number of focus groups:**

Twelve focus groups will be conducted.

**7. Amount and justification for any proposed incentive:**

Each participant in the pregnant/small children groups will receive a \$120.00 cash incentive, and each participant in the other groups will receive \$85.00 for their time and participation in the focus group. For the past several years, \$120.00 has been a standard market research industry rate for participation in a 90-minute focus group with hard-to-recruit participants such as pregnant women and women with small children. \$85.00 is the standard to recruit women of childbearing age.

**8. Questions of a Sensitive Nature:**

There will be no questions of a sensitive nature asked of participants.

**9. Description of Statistical Methods ( I.E. Sample Size & Method of Selection):**

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. The Contractor will contact prospective participants by telephone and screen them for eligibility to participate (see Appendix I). To maximize participation rates, recruiters will contact each potential participant at least five times to screen for eligibility and recruit for participation. Additionally, participants will receive a reminder call and confirmation letter before the groups convene.

**BURDEN HOUR COMPUTATION** (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

<b>Type/Category of Respondent</b>	<b>No. of Respondents</b>	<b>Participation Time (minutes)</b>	<b>Burden (hours)</b>
Pregnant women or women with small children	108	130	234
Women who are not pregnant and have not been pregnant in past 6 years but plan to become pregnant in next few years	36	130	78

**REQUESTED APPROVAL DATE:** December 2013

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**FDA CENTER:** CFSAN