Notice of Participation
OMB Control Number -- 0910-0191

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) states that agencies shall give interested and affected persons an opportunity to participate in and present their views in a formal evidentiary hearing, either personally or through a representative.

The Food and Drug Administration (FDA) is seeking OMB approval for the regulation that implements this statutory provision at 21 CFR 12.45, "Notice of Participation," which sets for the format and procedures for a person to file a notice of participation in a hearing.

A person who files a notice of participation must include their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. 21 CFR 12.45 also requires that the notice of participation include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or in the case of a hearing before a Public Board of Inquiry (21 CFR 13.25), concerning disclosure of data and information by participants.

2. Purpose and Use of the Information Collection

The presiding officer and other participants use the information collected to identify specific interests to be presented in a hearing. This preliminary information serves to expedite the pre-hearing conference and commits participation. In accordance with 21 CFR 12.45(e) the presiding officer may omit a participant's appearance.

3. Use of Improved Information Technology and Burden Reduction

FDA is considering developing ways individuals can submit petitions for notice of participation in hearings electronically.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of effort by Federal agencies has been identified and there is no similar data that can be used or modified for use.

5. Impact on Small Businesses or Other Small Entitites

This information collection does not impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

There is no collection frequency involved in this information collection.

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

There are no special circumstances for the collection of the 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), on December 29, 2008, (73 FR 79495), a 60-day notice for public comment was published in the FEDERAL REGISTER. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be provided to survey respondents.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality has been provided except as provided in 21 CFR 20.61 and generally considered in reviewing data and information submitted to FDA. Notices received by the agency are publicly available.

11. Justification for Sensitive Questions

No questions will be asked that are of a personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 792 hours annually.

Estimated Annual Reporting Burden					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	8	1	8	3	24

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

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 that incurred in reviewing the notice of participation. The agency estimates that the cost of a fully supported professional employee (GS-13/5) required to review such notices is $47 per hour.

21 CFR Section	Total Hours	Total Cost to Federal Government
12.45	24	$1,128

15. Explanation for Program Changes or Adjustments

The decrease in burden is due to the decrease in the average number of notices FDA received over the past three years.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results for this information collection.

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

We are requesting no exemption.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

n/a