

Notice of Participation
OMB Control Number -- 0910-0191

SUPPORTING STATEMENT

A. Justification

1. Circumstances Necessitating Information Collection

Section 701 of the Federal Food, Drug, and Cosmetic act (21 U.S.C. 371) (Attachment A) 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" (Attachment B), 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. How, By Whom, Purpose of 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. Consideration Given to Information Technology

FDA plans to develop ways individuals can submit petitions for notice of participation in hearings electronically.

4. Identification of 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. Small Businesses

This information collection does not impact on small businesses.

6. Less Frequent Information Collection

There is no collection frequency involved in this information collection.

7. Information Collection Circumstances

There are no special circumstances for the collection of the information.

8. Consultations with Persons Outside FDA

In accordance with 5 CFR 1320.8(d), on November 1, 2005, (70 FR 65904), a 60-day notice for public comment (Attachment C) was published in the Federal Register to which one comment was received from the public. However, it was not related to the information collection.

9. Payment or Gift

No payment or gift will be provided to survey respondents.

10. Confidentiality Provisions

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. Privacy

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

12. Burden of Information Collection

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 Responses	Total Hours
12.45	264	1	264	3	792

13. Costs to Respondents

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

14. Costs to 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 \$40 per hour.

21 CFR Section	Total Hours	Total Cost to Federal Government
12.45	792	\$31,680

15. Reason for Change

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

16. Statistical Reporting

There are no tabulated results for this information collection.

17. Display of OMB Approval Date

We are requesting no exemption.

18. Exceptions to “Certification for Paperwork Reduction Act Submissions”

These activities will comply with the requirements in 5 CFR 1320.9.