SUPPORTING STATEMENT
Notice of Participation (21 CFR Part 12.45)
OMB No. 0910-0191

SECTION A - JUSTIFICATION

1. Circumstances Necessitating Information Collection

In the past, one of the factors that contributed to the confusing and protracted nature of formal evidentiary public hearings was the presence of persons of ill-defined interest in the issues under consideration, whose participation was sporadic, and whose willingness to follow and comprehend the course of the proceeding was difficult to discern. Merely filing by notice of appearance, persons were able to place themselves on par with participants genuinely concerned with advancing the course of the hearing in relation to such matters as receiving copies of pleadings, arguments, notification of conferences, and other documents, even though their interests may have lapsed or their understanding of the issues was so tenuous as to preclude any useful purpose being served by their continued treatment as participants.

In an attempt to remedy this situation, the agency on April 13, 1979 (44 FR 22339) promulgated regulations governing Formal Evidentiary Public Hearings (21 CFR Part 12). Any interested person may participate in a hearing, either personally or through a representative, by filing a notice of participation under 21 CFR 12.45.

21 U.S.C. 371(a) and 21 CFR Section 12.45 (Attachment A) requires that any person filing a Notice of Participation state the person's specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice 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, in 21 CFR 13.25, concerning disclosure of data and information by participants. A participant's appearance can be struck by the presiding officer in accordance with § 12.45(e).

FDA is requesting OMB approval for:

> 21 CFR 12.45 - Notice of participation. Reporting Format of filing a Notice of Participation.

2. How, By Whom, Purpose of Collection

The information obtained is used by the presiding officer and other participants in a hearing to identify specific interests to be presented. This preliminary information serves to schedule, plan and expedite the prehearing conference and commits participation.

3. Consideration Given to Information Technology

The use of improved technology to reduce burden is not currently being used to prepare the notice of participation. There are plans in the future for accepting electronic submissions of the Notices.

4. Identification of Information

No duplication of effort by Federal agencies has been identified. There is no similar information that can be used or modified for use. The information required by filing a notice of participation is not available from any other source except the person filing.

5. Small Businesses

This information collection does not impact on small businesses.

6. Less Frequent Information Collection

The consequence of not having this information collection is that formal instructions and commitments for expediting active participation in a hearing would be lacking. The filing of notice of participation is based on a person's need to participate in a hearing. There is no regular number of times that a person is required to file; therefore, there are no consequences to Federal program or policy activities if the collection is conducted less frequently.

7. Special Information Collection Circumstances

There are no special circumstances that require the information to be collected in a manner inconsistent with the guidelines in 5 CFR 1320.6.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), on September 28, 1999 (64 FR 52331) a 60-day notice for public comment (Attachment B) published in the Federal Register. No comments were received from the public.

9. Payment or Gift

No payment or gift is contemplated under the terms of this proposed information collection.

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. Section 12.100 (a)(5) provides that all notices of participation filed under § 12.45 will be made part of the administrative record of a hearing. Section 12.105 further provides that documents in the administrative record will be publicly available.

11. Privacy

There are no questions of a sensitive nature involved in completing the Notice of Participation.

12. Burden of Information Collection

FDA receives an average of 30 notices of participation annually. Statements to be made in the notice are relatively straight-forward and the estimated preparation time of the notice is three hours. The total annual burden on all respondents, therefore, is calculated to be 90 hours.

FDA estimates the burden for this information collection to be as follows:

Estimated Annual Reporting Burden1					
CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	30	1	30	3	90

[1]There are no maintenance and operation costs nor start up and capital costs for this collection of information.

13. Costs to Respondent Resulting from the Collection of Information

Those familiar with the preparation of a Notice of Participation estimate the cost to the respondent to be $20,976. This cost is calculated on the basis of an average of three hours for preparation times an hourly rate of pay at $76 per hour (includes

professional, clerical work, and overhead). The total annual costs to all respondents is $76/reponse x 3 hours/response x 30 responses is estimated to be $6,840.

14. Annualized Cost to FDA

The estimated cost to the Federal Government is that incurred in the review of the notices. This amounts to an annual average of one hour per submission. 1 hr. per submission * 30 submissions = 30 hours. FDA estimates that the cost of a fully supported professional employee (GS-13, step 5) required to review such notices is $31.61 per hour. The estimated annual cost to the Federal Government to review such notices is $948.00 (30 x $31.61)

15. Reason for Change

A decrease of 186 hours in the estimated annual burden for this collection is a result of the decrease in the number of notices of participation FDA receives annually.

16. Statistical Reporting

The reporting requirements contained in this proposal are not statistical in nature and the records are not published for statistical use.

17. Display of OMB approval Date

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

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

There are no exceptions to "Certification for Paperwork Reduction Act Submissions" for this collection of information.

SECTION B - Collection of Information Employing Statistical Methods

The collection of data does not employ statistical methods.

Loose Ends: 0191

60 day notice: Lisa is reviewing and will get it back to me with revisions.

Item 8: Lisa will provide me with a paragraph about the survey of REGO initiatives that should support this item.

Item 12: Update the burden chart and explain how the burden was calculated. Jenny will e mail me the figures.

Item 13: Increase the costs 10% and refigure with the new burden figures.

Item 14: Refigure the costs with new hourly wage and the new burden figures.

Item 15: Explain the changes in the burden and cost.

Sign certification form.