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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4069]

Agency Information Collection Activities: Proposed Collection; Comment Request; Notice of Participation; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for filing a notice of participation with FDA.

DATES: Submit written comments on the collection of information by (*insert date 60 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191—Extension)

Under part 12 (21 CFR part 12) regulations issued under sections 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393), any interested person may participate in a formal evidentiary hearing, either personally or through a representative by filing a notice of participation under § 12.45. Section 12.45 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 § 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).

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 expedite the prehearing conference and commits participation.

The affected respondents are individuals or households, State or local governments, not-for-profit institutions and businesses or other for-profit groups and institutions.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 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 capital costs or operating and maintenance costs associated with this collection of information.

The agency bases this estimate on an average for the period 1996 through 1998 in which each notice of participation filed took an estimated 3 hours to complete.

Dated: 9/22/99
September 22, 1999



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

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