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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4329]

Agency Information Collection Activities; Proposed Collection; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 requirements for filing objections and requests for a hearing on a regulation or order.

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. Capezzuto, 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.

Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12 (OMB Control Number 0910–0184—Extension)

Under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), within 30 days after publication of a regulation or order, any person adversely affected by such regulations or order may file objections and request a public hearing. The implementing regulations for these statutory requirements are found at 21 CFR 12.22, which sets forth the format and instructions for filing objections and requests for a hearing. Each objection for which a hearing has been requested must be separately numbered and specify with particularity the provision of

the regulation or the proposed order objected to. In addition, each objection must include a detailed description and analysis of the factual information to be presented in support of the objection as well as any report or other document relied on, with some exceptions. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis only for the purpose of determining whether a hearing request is justified. The description and analysis do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	60	1	60	20	1,200

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on agency data received on this administrative procedure for the past 3 years. Agency personnel responsible for processing

the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately 60 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: October 18, 1999



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

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