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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. FDA-2008-N-0653]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0184. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

The regulations in 21 CFR 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), set forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d) (21 CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and 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.

In the **Federal Register** of January 14, 2009 (74 FR 2080), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

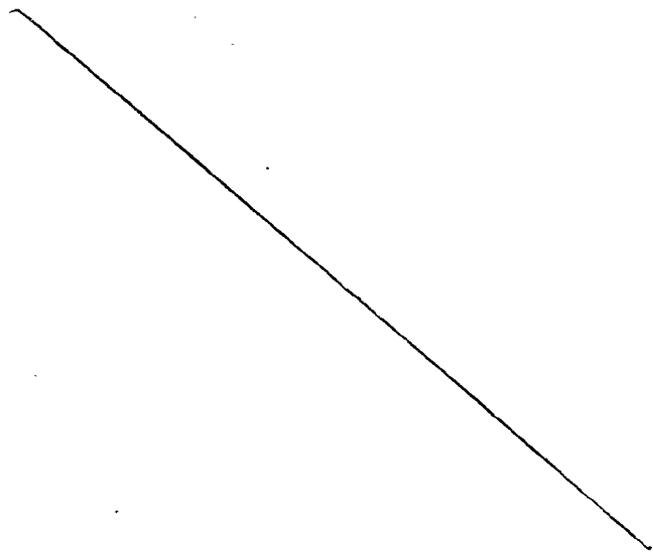
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TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	5	1	5	20	100

<sup>1</sup>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 past filings. Agency personnel, responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately five requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.



Dated: **MAR 27 2009**  
March 27, 2009.

*Jeffrey Shuren*

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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

[FR Doc. 09-????? Filed ??-??-09; 8:45 am]

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*Matthew Jehr*

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