Filing Objections and Requests for a Hearing on a Regulation or Order

0910-0184

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2) states that on or before the thirtieth day after the date on which an order is made public, any affected persons may file objections on the provisions of the order and may request a hearing.

The Food and Drug Administration (FDA) is seeking the Office of Management and Budget (OMB) approval for the regulations that implement these statutory provisions at 21 CFR 12.22, Filing objections and request for a hearing on a regulation or order. This regulation sets forth the format and procedures by which a person may submit to the Commissioner of FDA, written objections and a request for a hearing.

2. Purpose and Use of the Information Collection

The information obtained is used by FDA to determine if a hearing is justified. It may also be used to justify modification or revocation of a regulation or order.

3. Use of Improved Information Technology and Burden Reduction

FDA is considering developing ways individuals can submit petitions and requests electronically.

4. Efforts to Identify Duplication and Use of Similar 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. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8a. Publication in the FEDERAL REGISTER

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of September 9, 2011 (76 FR 55922) to which the Agency received two comments. However, these comments did not address the information collection.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be provided.

10. Assurance of Confidentiality Provided to Respondents

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. Petitions received by the Agency are publicly available.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 60 hours annually.

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
12.22	3	1	3	20	60

13. Estimates of Other Total Annual Costs to Respondents and Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal government is that incurred in reviewing the requests for objections and requests filed for a hearing on a regulation or order, as well as preparing the Agency's response. The Agency estimates that the cost of a fully supported professional employee (GS-13/5) required to review such requests and petitions, and prepare the response is $48.35 per hour. The estimate of the cost to the government is $2,901.

21 CFR Section	Total Hours	Total Cost to Federal Government
12.22	60	$2,901

15. Explanation for Program Changes or Adjustments

This program change is a result of fewer objections and requests for hearings received by the Agency.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

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

There are no exceptions to the certification.