

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of
Action; Advisory Opinions
OMB Control Number -- 0910-0183

SUPPORTING STATEMENT

A. Justification

1. Circumstances Necessitating Information Collection

The Administrative Procedures Act at 5 U.S.C. 552(a)(1)(C) (Attachment A) states that agencies shall make available to the public information on the rules, format, and content required of all papers, reports or examinations pertaining to agency rules, opinions, orders, records, and proceedings. Further, the Administrative Procedures Act at 5 U.S.C. 553(c) and 5 U.S.C. 553(e) (Attachment A) states that agencies shall give interested persons an opportunity to participate in rulemaking through the submission of written data, views, or arguments with or without the opportunity for oral presentation; and, that each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

The Food and Drug Administration (FDA) is seeking OMB approval for the regulations that implement these statutory provisions at 21 CFR 10.30, 10.33, 10.35, and 10.85 (Citizen Petitions, Petition for Administrative Reconsideration of Action, Petition for Administrative Stay of Action, and Advisory Opinions (Attachment B)).

2. How, By Whom, Purpose of Collection

In the case of §10.85, the information is used by the agency to determine whether there is sufficient public interest on a matter of general applicability to justify the issuance of a formal advisory opinion which the agency is obligated to follow unless there is an immediate and significant danger to health. Pertaining to §§10.30, 10.33, and 10.35 the agency uses the information to determine if it is feasible to grant the reconsideration or stay of action.

3. Consideration Given to Information Technology

FDA plans to develop ways individuals can submit petitions and requests electronically.

4. Identification of 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. Small Businesses

This information collection does not impact on small businesses.

6. Less Frequent Information Collection

There is no collection frequency involved in this information collection.

7. Information Collection Circumstances

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

8. Consultations with Persons Outside FDA

In accordance with 5 CFR 1320.8(d), on November 16, 2005, (70 FR 69574), a 60-day notice for public comment (Attachment C) was published in the Federal Register. No comments were received from the public.

9. Payment or Gift

No payment or gift will be provided to survey respondents.

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. Petitions received by the agency are publicly available.

11. Privacy

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

12. Burden of Information Collection

The total annual estimated burden imposed by this collection of information is 6,108 hours annually.

Estimated Annual Reporting Burden					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours
10.30	156	3	468	12	5,616
10.33	10	2	20	10	200
10.35	13	2	26	10	260
10.85	2	1	2	16	32

Estimated Annual Reporting Burden		
TOTAL		6,108

13. Costs to Respondents

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

14. Costs to Federal Government

The estimated cost to the Federal government is that incurred in reviewing the requests for advisory opinions, citizen petitions, and petitions for reconsideration or stay of action, 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 \$40 per hour.

21 CFR Section	Total Hours	Total Cost to Federal Government
10.30	5,616	\$224,640
10.33	200	8,000
10.35	260	10,400
10.85	32	1,280
TOTAL	6,108	\$244,320

15. Reason for Change

The increase in burden is due to the increased number of petitions received at FDA. In the cases of §10.33 and §10.35, the increase is due to the submission of more than one petition from the same source.

16. Statistical Reporting

There are no tabulated results for this information collection.

17. Display of OMB Approval Date

We are requesting no exemption.

18. Exceptions to “Certification for Paperwork Reduction Act Submissions”

These activities will comply with the requirements in 5 CFR 1320.9.