

INFORMATION COLLECTION REQUEST for
CITIZEN PETITION
OMB NUMBER 0910-0183
Supporting Statement

A. JUSTIFICATION:

1. Circumstances Necessitating Information Collection

The Administrative Procedures Act, 5 U.S.C. 553(3) (Attachment A) provides that agencies shall give interested persons an opportunity to participate in the rule making through the submission of written data, views, or arguments with or without the opportunity for oral presentation. Accordingly, 21 CFR 10.30 (Attachment B) provides that any person may submit to the agency a citizen petition requesting the Commissioner, Food and Drug Administration, to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

In the past, there had been no form or other procedural requirements relating to a citizen petition. This resulted in confusion and uncertainty on the part of those who wish to petition the agency on a particular matter, as well as on the part of those in the agency who have received various forms of requests and have been unable to determine how they should be handled.

The provisions of section 10.30 do not apply to routine correspondence, but are reserved for those specific matters where, perhaps after informal discussion and correspondence, a member of the public concludes that a formal proceeding should be initiated to resolve a particular matter. These matters specifically raised in a formal petition submitted pursuant to section 10.30 require a formal response by the Commissioner.

FDA is requesting for approval of:

21 CFR 10.30 -- Citizen Petition. Reporting format for submitting a Citizen
Petition.

2. How, By Whom, Purpose of Information Collection

This information is used by the agency to determine the need or desirability of the requested action and also to determine if the submitted information is sufficient to support the action. FDA determines whether or not to grant the petition based on the information submitted.

3. Consideration Given to Information Technology

The use of improved technology to reduce burden is not applicable to filing of Citizen Petitions. There are plans in the future for accepting electronic submissions of Citizen Petitions.

4. Identification of Information

No duplication of effort by Federal agencies has been identified. There is no similar information that can be used or modified for use. The information required by filing a Citizen Petition is not available from any other source except the person filing.

5. Small Business

This information collection does not impact on small businesses.

6. Less Frequent Information Collection

If these procedural requirements were not provided, citizens would be unable to determine how to go about submitting a petition to FDA for the issuance, amendment, or repeal of a rule. There is no minimum or maximum number of times that a person is required to petition; therefore, there are no consequences to Federal program or policy activities if the collection is conducted less frequently.

7. Special Information Collection Circumstances

There are no special circumstances that require the information to be collected in a manner inconsistent with the guidelines in 5 CFR 1320.6.

8. Consultations with Persons Outside FDA

In accordance with 5 CFR 1320.8(d), on August 12, 1999 (64 FR 44018) 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 is provided under the terms of this information collection.

10. Confidentiality Provisions

There are no questions of a sensitive nature, and 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.

11. Privacy

There are no questions of a sensitive nature involved in this information collection.

12. Burden of Information Collection

Burden may vary from 2 hours for a simple petition to 40 hours for a petition requiring extensive literature review and compilation of information. It is estimated that the average petitions would take 12 hours to file.

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

Table 1. -- Estimated Annual Reporting Burden ¹					
21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	120	1	120	12	1,440

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

13. Cost to Respondents

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

14. Cost to Federal Government

The cost to the Federal Government is that required to review the petition and determine the action to be taken. It takes an average of 8 hours per citizen petition (ranging from 1 to 16 hours). FDA estimates that the cost of a fully supported professional employee GS 13/5, earning \$32 per hour, required to review 960 petitions per year would ensue \$30,720 in review costs. If the petition is denied, then the time will double. If the petition results in a regulation, the average cost per regulation is calculated as follows:

Initial Review of Petition:

8 hours x 120 petitions = 960 hours
960 hours x \$32 = 30,720

Time to develop NPRM - 2 person years

2,087 hours x \$32 x 2 = \$133,568

Time to develop Final Rule - 1 person year

2,087 hours x \$32 = \$66,784

15. Reason for Change

There is no change in this information collection.

16. Statistical Reporting

The reporting requirements contained in this proposal are not statistical in nature and the records are not published for statistical use.

17. Display of OMB Approval Date

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

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

There are no exceptions to “Certification for Paperwork Reduction Act Submissions” for this information collection.