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 Making the Collection of Information Necessary

The Administrative Procedures Act at 5 U.S.C. 552(a)(1)(C) 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) states that Agencies shall give interested persons an opportunity to participate in rulemaking through the submission and subsequent follow-up submissions 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 the Office of Management and Budget (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.)

2. Purpose and Use of the Information 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. Use of Improved Information Technology and Burden Reduction

FDA has developed a method for electronic submission of citizen petitions. The Agency still allows for non-electronic submissions, however, electronic submissions of a citizen petition to a specific electronic docket presents a simpler and straightforward approach. FDA has created a single docket on http://www.regulations.gov, the U.S. Government's consolidated docket Website for Federal Agencies, for the initial electronic submission of all citizen petitions. The advantage to this change is that it ensures efficiency and ease in communication, quicker interaction between citizen petitioners and FDA, and easier access

to FDA to seek input through the citizen petition process.

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 is no collection frequency involved in this information collection.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of March 20, 2014 (79 FR 15594) to which the Agency received one comment. However, this comment did not address the information collection.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be provided to survey respondents.

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 will be 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 5,122 hours annually.

Table 1. – Estimated Annual Reporting Burden[1]					
21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
10.30	207	1	207	24	4,968
10.33	4	1	4	10	40
10.35	5	1	5	10	50
10.85	4	1	4	16	64
Total					5,122

13. Estimates of Other Total Annual Costs to Respondents and/or 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 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 $48.35 per hour. The estimate of the cost to the government is $247,649.

21 CFR Section	Total Hours	Total Cost to Federal Government
10.30	4,968	$240,203
10.33	40	1,934
10.35	50	2,418
10.85	64	3,094
Total	5,122	$247,649

15. Explanation for Program Changes or Adjustments

While there is no change to the burden estimates this ICR is characterized as a revision because FDA has developed a method for electronic submission of citizen petitions. The Agency still allows for non-electronic submissions, however, electronic submissions of a

citizen petition to a specific electronic docket presents a simpler and straightforward approach. FDA has created a single docket on http://www.regulations.gov, the U.S. Government's consolidated docket Website for Federal Agencies, for the initial electronic submission of all citizen petitions. The advantage to this change is that it ensures efficiency and ease in communication, quicker interaction between citizen petitioners and FDA, and easier access to FDA to seek input through the citizen petition process.

16. Plans for Tabulation and Publication and Project Time Schedule

    There are no tabulated results for this information collection.

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

    FDA is requesting no exemption.

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

    There are no exceptions to the certification.