Administrative Practices and Procedures; Formal Evidentiary Public Hearing

0910-0191

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Administrative Procedures Act (5 U.S.C. 553(e)) provides that every Agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) states that Agencies shall give interested and affected persons an opportunity to participate in and present their views in a formal evidentiary hearing, either personally or through a representative.

The Food and Drug Administration is seeking the Office of Management and Budget (OMB) approval for the information collection contained in the regulations that implement these statutory provisions:

21 CFR 10.30 -- Citizen petition

Sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20) (Submission of documents to Division of Dockets Management), a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

21 CFR 10.33 -- Administrative reconsideration of action

Sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under 21 CFR 10.25 (Initiation of administrative proceedings). A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies.

21 CFR 10.35 -- Administrative stay of action

Sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (Submission of documents to Division of Dockets Management), the Commissioner to stay the effective date of any administrative action.

21 CFR 10.85 -- Advisory opinions

Sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (Submission of documents to Division of Dockets Management), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the formal position of FDA on a matter of general applicability.

21 CFR 12.22 -- Filing objections and requests for a hearing on a regulation or order

Sets 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)).

21 CFR 12.45 -- Notice of participation

Sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard.

2. Purpose and Use of the Information Collection

The presiding officer and other participants use the information collected to identify specific interests to be presented in a hearing. This preliminary information serves to expedite the pre-hearing conference and commits participation. In accordance with 21 CFR 12.45(e) the presiding officer may omit a participant's appearance.

3. Use of Improved Information Technology and Burden Reduction

FDA is considering developing ways individuals can submit petitions for notice of participation in hearings 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 Entitites

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 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 December 10, 2014 (79 FR 73320). No comments were received.

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. Notices 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

12a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this collection of information is 12 hours annually.

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
10.30-- Citizen Petition	207	1	207	24	4,968
10.33-- Administrative reconsideration of action	4	1	4	10	40
10.35-- Administrative	5	1	5	10	50

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Stay of Action					
10.85--Advisory Opinions	4	1	4	16	64
12.22--Filing Objections and Requests for a Hearing on a Regulation or Order	3	1	3	20	60
12.45--Notice of Participation	4	1	4	3	12
Total					5,194

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

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 collection.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal government is that incurred in reviewing the notice of participation, 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 notices is $49.32 per hour.

21 CFR Section	Total Hours	Total Cost to Federal Government
10.30-- Citizen Petition	4,968	$245,021
10.33--Administrative reconsideration of action	40	1,973
10.35--Administrative Stay of Action	50	2,466
10.85--Advisory Opinions	64	3,156
12.22--Filing Objections and Requests for a Hearing on a Regulation or Order	60	2,959
12.45--Notice of Participation	12	592
TOTAL		$256,167

15. Explanation for Program Changes or Adjustments

The program change resulting in a burden increase is due to the consolidation of 0910-0183, 0910-0184 and 0910-0191 as these all deal with administrative procedures.

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

    We are requesting no exemption.

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

    There are no exceptions to the certification.