

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration's regulation (21 CFR 10.85) (Attachment A) establishes a procedure whereby any interested person may request a formal advisory opinion from the commissioner of Food and Drugs on a matter of general applicability. The regulation sets out the format with instructions for making such requests.

In the request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested and a full statement of all facts and legal points relevant to the request, whether favorable or unfavorable to the position of the petitioner.

If the request for a formal advisory opinion is granted, the opinion represents the formal position of FDA on a matter of general applicability. Absent an immediate and significant danger to health, the agency is obligated to follow the opinion until it is amended or revoked.

The procedures in 21 CFR 10.85 do not apply to request for the informal opinions of agency officials which represent their best information and advice and which do not bind or commit the agency to the views expressed.

FDA is requesting OMB approval for the information collection requirements in petitioning the agency for an advisory opinion:

21 CFR 10.85 - Reporting: Specifies the format for requesting advisory opinions from the Commissioner on a matter of general applicability.

2. How, By Whom, Purpose of Collection

This information is used by the agency to determine whether there is a sufficient public interest on a matter of general applicability to justify the issuance of a formal advisory opinion that the agency is obligated to follow unless there is an immediate and significant danger to health.

3. Consideration Given to Information Technology

The use of improved technology to reduce burden is not currently available for filing of advisory opinions. There are plans in the future for accepting electronic submissions for requests of advisory opinions.

4. Identification of Information

There is no similar information that can be used or modified for use. The information required in petitioning the agency for an advisory opinion is not available from any other source except the person petitioning.

5. Small Businesses

The request for advisory opinions is a straight-forward set of instructions and format to obtain the information concerning the specific matter of general applicability for which an advisory opinion is sought. The request may be used by small businesses and other small entities without need for modification.

6. Less Frequent Information Collection

The consequences of not having this information collection is that interested persons would not have the ability to request the agency to commit to a particular course of regulatory action.

7. 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 September 28, 1999 (64 FR 52329), a 60-day notice for public comment (Attachment B) 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

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. A request for advisory opinion is included in the administrative record and is publicly available.

11. Privacy

There are no questions of a sensitive nature involved in completing the request for advisory opinion.

12. Burden of Information Collection

The Agency receives an average of three requests for advisory opinions per year. It is estimated that the average request requires 16 hours to complete. Therefore, the total annual burden is calculated to be 48 hours (3 requests x 16 hours per request = 48 total burden hours).

The total annual estimated burden imposed by this collection of information is 48 hours annually.

Estimated Annual Reporting Burden					
21 CFR	No. of Respondents	No. Of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
10.85	3	1	3	16	48

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

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 and preparing the agency's response. As determined by knowledgeable persons, this amounts to an annual average of 16 hours per request for an advisory opinion. 48 hours per request * 3 requests per year equals 48 hours. FDA estimates that the cost of a fully supported professional employee (GS 13/5) required to review such request and prepare the response is \$31.61 per hour. The estimated annual cost to the Federal Government to respond to requests for an advisory opinion is \$1,517.28 (48 hours * \$31.61/hour).

15. Reason for Change

The burden estimate for this collection of information is based on agency data received on this administrative procedure for the past three years. The reduction of 80 burden hours is due to the decrease in requests filed with the agency for advisory opinions.

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 collection of information.

B. JUSTIFICATION

1. This collection of information does not employ statistical methods.