UNITED STATES FOOD AND DRUG ADMINISTRATION

Administrative Practices and Procedures;
Formal Hearings

OMB Control No. 0910-0191 - Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations found in 21 CFR Part 10, 21 CFR Parts 12 through 16, and 21 CFR Part 19 (21 CFR §§ 10, 12-16, and 19), which implement general provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The regulations were promulgated in accordance with the Administrative Procedures Act and establish administrative practice and procedures to give instructions to those conducting business with FDA. Regulations in part 10 (21 CFR Part 10) describe general administrative practices and include content and format instruction on submitting information to the agency, petitions for agency action, and other topics such as the public calendar. Regulations in 21 CFR parts 12 through 16 cover formal evidentiary, public, and regulatory hearings. We also account for burden associated with waiver requests under 21 CFR part 10.19. Unless a waiver, suspension, or modification submitted under § 10.19 (21 CFR 10.19) is granted by the Commissioner of Food and Drugs (the Commissioner), the regulations in 21 CFR part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Although we have not received requests under § 10.19, to reflect the attendant burden resulting from submitting such a request, we provide an estimate of 1 response and 1 burden hour annually, as reflected in Question-12 of this supporting statement. Also, because most information associated with regulations in parts 12-16 is obtained during the conduct of an official administrative action as described under 5 CFR 1320.4, we only include burden associated with initiating hearings pursuant to the applicable regulations.

The information collection also includes activities and burden associated with general meeting requests and correspondence submitted under section 10.65 (21 CFR 10.65), as well and general submissions associated with section 10.115 – which provides for public participation in the development of agency guidance documents through requests to our Dockets Management Staff. Although most submissions and attendant burden associated with recommendations found in FDA guidance documents is accounted for in topic-specific and approved ICRs, here we account for burden associated with general public submissions as described in § 10.115(f)(3).

The information collection also includes burden associated with recommendations discussed in the guidance document entitled, "*Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act."* The guidance document communicates FDA's interpretation of section 505(q) of the Federal Food, Drug, and

Cosmetic Act (FD&C Act) (21 U.S.C. 355(q)): *Petitions and Civil Actions Regarding Approval of Certain Applications*. The guidance identifies and discusses submission elements including certification, as well as verification of supplemental information. It also addresses the relationship between the review of petitions and pending ANDAs, 505(b)(2) applications, and 351(k) applications for which a decision on approvability has not yet made.

We are revising the information collection to include requests for FDA speakers. As communicated on our website at https://www.fda.gov/training-and-continuing-education/contacts-requesting-fda-speaker, FDA receives thousands of requests each year from trade associations and industry-based groups for speakers to participate in external meetings, conferences, and workshops. To facilitate the processing of these requests and determine participation, we have designated contacts throughout the agency and have developed web-based request templates as follows:

To request cross-agency speakers from FDA:

- How to submit cross-agency requests
- Requesting cross-agency speakers from FDA

To request an FDA speaker from one of our centers or offices:

Center for Biologics Evaluation and Research

- FDA/CBER Speaker Request/Invitation
- Procedures for Requesting Speakers for FDA/CBER for Meetings, Conferences, Panels, Workshops

Center for Drug Evaluation and Research

- Requesting Speakers from CDER

Center for Devices and Radiological Health

- Requesting Speakers from CDRH

Center for Food Safety and Applied Nutrition

- Contact CFSAN
- Speaker or meeting requests from foreign competent authorities should be sent directly to FDA-CFSAN-International-Engagement@fda.hhs.gov

Center for Tobacco Products

- Formal Correspondence and Meeting Requests: AskCTP@fda.hhs.gov.
    - Also submit a draft agenda and attendee list.

- Requesting Speakers from CTP

Center for Veterinary Medicine

- Contact CVM

Office of Digital Transformation (ODT)

- FDA/OC/ODT Speaker Request/Invitation

Office of Regulatory Affairs

- Contact ORA

We are therefore requesting OMB approval for the information collection provisions found in our general administrative regulations in 21 CFR subchapter A, the associated guidance document identified herein, and the web-based speaker requests specifically discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use the information collection in support of agency operations to determine and direct as appropriate throughout the agency, requests for FDA action; to plan and coordinate agency efforts in responding to such requests; and to best utilize agency resources to promote and administer protections to the public health. The data from petitions and other requests received by the agency helps us identify areas of both interest and concern to those who consume the products regulated by FDA.

3. Use of Improved Information Technology and Burden Reduction

Most business with FDA is conducted electronically reflecting current standard business practice. Where possible and as resources permit, we continually seek ways to improve operational efficiencies with available technologies and user applications, as well as the most cost effective implementation methods. We routinely invite and encourage ideas and comments in this regard in notices published by the agency.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection does not pose undue burden on small entities. Provisions in part 10.19 (21 CFR § 10.19) allow for waived, suspended, or modified procedures. In addition, we provide resources and instruction on our website at www.fda.gov regarding submissions to FDA.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden. This information collection is established and maintained to support requests *of* the agency and provide for public participation in agency activities. The collection schedule is determined by respondents.

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the Federal Register of February 27, 2023 (88 FR 7981). Although two comments were received, neither was directly responsive to the information collection topics solicited. At the same time, the comments were supportive of FDA information collection activity and we appreciate this input.

Also, our regulations at 21 CFR § 10.115 provide for the development and issuance of agency guidance documents intended to assist respondents with information collection activity undertaken by the agency and provide for public comment at any time.

9. Explanation of Any Payment or Gift to Respondents

No gift or payment is provided to respondents to the information collection.

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

The information collection contains no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Burden:

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
10.19--request for waiver, suspension, or modification of requirements	7	1	7	1	7
10.30 and 10.31--citizen petitions and petitions related to ANDAs certain NDAs[2], or certain BLAs[3]	200	1	200	24	4,800
10.33--administrative reconsideration of action	9	1	9	10	90
10.35--administrative stay of action	12	1	12	10	120
10.65--meetings and correspondence	37	1	37	5	185
10.85--requests for Advisory opinions	1	1	1	16	16
10.115(f)(3)--submitting draft guidance proposals	26	1	26	4	104
12.22--Filing objections and requests for a hearing on a regulation or order	18	1	18	20	360
12.45--Notice of participation	5	1	5	3	15
External requests for FDA speakers	3,900	1	3,900	0.17 (10 minutes)	663
Total			4,215		6,360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] New drug applications.
[3] Biologics license applications.

We have updated our figures since last OMB approval to reflect submissions to our Division of Dockets Management for the respective activities. In addition, we tallied speaker requests received by the various components within FDA to cover this newly added element.

12b. Annualized Hour Cost Estimate

We estimate an average cost of $100,000 annually for the information collection by multiplying the total annual hours (6,360) by a factor of $10/hr in excess of the Federal minimum wage in to include costs of mailing and copying that may be incurred if applicable, to calculate total annual costs to respondents of $109,710.

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

We estimate the annual cost to the Federal government to be $469,972.50 annually, by multiplying the number of submissions (4,215) by an hourly wage rate of $55.75 (to reflect the Washington D.C. area salary of a GS-13/5 FTE who would process the submission). We then double this figure to account for overhead costs.

15. Explanation for Program Changes or Adjustments

The information collection reflects nominal adjustments to individual activities that correspond to the applicable provisions. We have also added 3,900 responses and 663 hours, annually, to reflect burden we believe is associated with requests to FDA for speaker participation at an external agency events. As a result of these adjustments, the information collection reflects an annual increase in responses of 3,119 and an annual decrease in hours of 3,360.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish this collection of information.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to the Certification under 5 CFR 1320.9

There are no exceptions to the certification.