United States Food and Drug Administration

Administrative Practices and Procedures; Formal Hearings

OMB Control No. 0910-0191 -- EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None.

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 instructions 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 been made.

The information collection also includes burden associated with Section 562 of the FD&C Act (21 U.S.C. 360bbb-1) directs FDA to establish adequate dispute resolution (DR) procedures to ensure appropriate review of scientific controversies between FDA and members of regulated industry, including possible scientific advisory committee review. To implement this provision, we amended the general appeal regulation applicable across all FDA components (§ 10.75 (21 CFR 10.75), *Internal agency review of decisions*) to provide for advisory committee review (§ 10.75(b)(2)). Disputes may involve complex judgments and issues that are scientifically or technologically important so it is critical to have procedures in place that will encourage open, prompt discussion of disputes and lead to their resolution. We have developed guidance that describes dispute procedures related to handling requests for decisions affecting animal drugs or other products for animals. To assist respondents in dispute resolution affecting animal drugs or other products that are regulated by Center for Veterinary Medicine (CVM), we have developed the guidance entitled, "*Guidance for Industry (GFI) #79, "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine*", (July 2005). (Previously, this information collection was approved under OMB control no. 0910-0566).

The information collection also includes burden associated with requests for FDA speakers. 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 which can be found on our website at https://www.fda.gov/training-and-continuing-education/contacts-requesting-fda-speaker.

We therefore request OMB extension of OMB approval of the information collection provisions found in our general administrative regulations in 21 CFR subchapter A as 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 reducing 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

FDA published a 60-day notice for public comment in the *Federal Register* of April 7, 2026 (91 FR 17658). Three comments were received. One comment was not responsive to the questions posed in § 1320.8(d). Two comments supported the collection of information, however, one commentor stated that our time estimates for citizen petitions seemed low. They also suggested our online submission system could be easier to use and that simple templates or examples would be helpful.

FDA appreciates the comments. We base our estimates regarding citizen petitions on our historical experience. However, we will continue to monitor and make changes as evidence warrants. Currently, FDA provides a number of guidance documents and templates to assist with submissions:

1. 21 CFR Part 10.30 – provides a template of the format and information needed to submit a citizen petition.
2. 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 identifies and discusses submission elements including certification, as well as verification of supplemental information.
3. A list of contacts and request templates can be found on our website at https://www.fda.gov/training-and-continuing-education/contacts-requesting-fda-speaker.
4. Information regarding small business assistance can be found on our website at https://www.fda.gov/industry/small-business-assistance.

Additionally, we note that in the published 60-day and 30-day notices, FDA inadvertently left out the burden regarding the guidance document entitled "*GFI #79 Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine*." We have accounted for the burden in question 12 of this supporting statement.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a)

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity. The PII submitted via Regulations.gov is name, email address, and mailing address. The FDA Privacy Office has determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public (see 21 CFR 20), consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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	2	1	2	1	2
10.30 and 10.31--citizen petitions and petitions related to ANDAs[2] certain NDAs[3], or certain BLAs[4]	330	1	330	24	7,920
10.33--administrative reconsideration of action	13	1	13	10	130
10.35--administrative stay of action	28	1	28	10	280
10.65--meetings and correspondence	18	1	18	5	90
10.75 – internal reviews of agency decisions	4	1	4	10	40
10.85--requests for Advisory opinions	3	1	3	16	48

10.115(f)(3)--submitting draft guidance proposals	1	1	1	4	4
12.22--Filing objections and requests for a hearing on a regulation or order	15	1	15	20	300
12.45--Notice of participation	1	1	1	3	3
External requests for FDA speakers	3,900	1	3,900	0.17 (10 minutes)	663
Total			4,315		9,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Abbreviated New Drug Applications.
[3] New Drug Applications.
[4] 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.

12b. Annualized Cost Burden Estimate

We estimate an average cost of $100,000 annually for the information collection by multiplying the total annual hours (9,440) 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 $162,840.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

We estimate an average cost of $100,000 annually for the information collection by multiplying the total annual hours (9,440) 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.

14. Annualized Cost to the Federal Government

We estimate the annual cost to the Federal government to be $400,432 annually, by multiplying the number of submissions (4,315) by an hourly wage rate of $46.40 (to reflect the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA area salary of a GS-11/5 FTE who would process the submission). We then doubled 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.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.