4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-6085]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Administrative Practice and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with our General Administrative Practice and Procedures regulations.

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].** The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF**

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-6085 for "General Administrative Practice and Procedures." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

General Administrative Practice and Procedures

OMB Control Number 0910-0191--Revision

This information collection supports FDA regulations governing its administrative practices and procedures. Although certain information collection pertaining to official administrative actions is not subject to review by OMB under the PRA in accordance with 44 U.S.C. 3518(c)(1)(B) (5 CFR 1320.4(a)(2)), we have reviewed our regulations and are revising this information collection to include provisions that we believe may be subject to OMB review. We are also revising the information collection to consolidate related activities discussed in Agency guidance, as we believe this will improve the efficiency of our operations.

We estimate the burden of this collection of information as follows:

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	1	1	1	1	1
10.30 and 10.31; citizen petitions and petitions related to ANDA[2], certain NDAs[3], or certain BLAs[4]	220	1	220	24	5,280
10.33; administrative reconsideration of action	6	1	6	10	60
10.35; administrative stay of action	6	1	5	10	50
10.65; meetings and correspondence	750	1	750	5	3,750
10.85; requests for Advisory opinions	4	1	4	16	64
10.115(f)(3); submitting draft guidance proposals	100	1	100	4	400
12.22--Filing objections and requests for a hearing on a regulation or order	5	1	5	20	100
12.45--Notice of participation	5	1	5	3	15
Total			1,096		9,720

[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.] Biologic License Applications

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. Because we have not received requests under § 10.19, we had not included this provision in the information collection. However, to reflect the attendant burden resulting from submitting such a request, we provide an estimate of 1 response and 1 burden hour annually.

Administrative proceedings may be initiated under § 10.25 when a petition is submitted. Section 10.30 sets forth procedures by which an interested person may submit 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. Similarly, section 10.31 governs citizen petitions and petitions for stay of action related to abbreviated new drug applications, certain new drug applications, or certain biologics license applications issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(a)). The regulations provide content, format, and procedural requirements applicable to the submission of these petitions. To assist respondents to the information collection, FDA's Center for Drug Evaluation and Research developed an interpretive guidance entitled, "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." The guidance describes FDA's current thinking on interpreting section 505(q) of the FD&C Act (21 U.S.C. 355(q)), and is currently approved under OMB control number 0910-0679. Based on Agency data, an average of 220 citizen petitions are received annually under

§§ 10.30 and 10.31, and we estimate an average of 24 hours is required to prepare such a petition, for a total of 5,280 hours annually.

The regulations also establish a means by which an interested person may request that part or all of a decision by the Commissioner be reconsidered, or that the effective date of an action be stayed or extended. Sections 10.33 and 10.35 establish the content, format, and procedural requirements applicable to such requests and explain that they must be submitted no later than 30 days after the decision involved. The regulations provide alternatively that, for good cause, the Commissioner may permit a petition to be filed after 30 days. The regulations also explain that an interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. According to our records, we have received a total of 12 such requests and we assume it takes respondents an average of 10 hours to prepare.

Section 10.65 covers Agency meetings and correspondence. Interested persons may hold meetings and exchange correspondence with FDA representatives on matters within its jurisdiction by following the instructions and providing the information described in § 10.65. Because FDA maintains other information collections in its inventory that cover specific types of meeting requests, we did not previously include burden that may result from this section. However, to account for burden associated with meeting requests and correspondence generally, we provide an estimate of 2,000 submissions annually under this information collection; we assume one respondent per submission; and we assume each submission requires respondents anywhere between 1 to 10 hours to prepare, including gathering and reviewing the necessary material. We therefore use an average of 5 hours for this estimate and base this estimate on our experience with similar information collection.

Section 10.85, issued under section 701(a) of the FD&C Act, sets forth content, format, and procedural requirements by which an interested person may request an advisory opinion from the Commissioner on a matter of general applicability. The regulation explains that, when making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Based on Agency data, we estimate 4 such requests are received each year and we assume each request requires 16 hours to prepare, for a total of 64 hours annually.

Section 10.115(f)(3) provides for the public submission of draft guidance documents or topics for development to our Dockets Management Staff. To participate in the development and issuance of guidance documents, the public may elect to submit comment through alternative mechanisms as explained in our Good Guidance Practice regulations under § 10.115. Although most submissions and attendant burden associated with recommendations found in Agency guidance is accounted for in individual information collections associated with a particular product area or regulatory topic, here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3). Based on Agency data, we receive an average of 100 such submissions each year; we assume each submission requires an average of 4 hours to prepare; and therefore calculate a total burden of 400 hours annually.

Regulations in 21 CFR 12.20 (§ 12.20) include information collection associated with requesting a formal evidentiary public hearing, and are issued under section 701(e)(2) of the FD&C Act. The regulations provide instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In

addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and does not limit the evidence that may be presented if a hearing is granted. We estimate 5 respondents will file a request under the regulation and assume each request requires 20 hours to prepare, for a total of 100 hours annually.

Finally, section 12.45 (21 CFR 12.45), issued under section 701 of the FD&C Act, sets forth content, format, and procedural requirements 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. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance. Based on our records, we estimate 5 filings under this regulation and assume it requires 3 hours to prepare, for a total of 15 hours annually.

Respondents to the information collection are those interested persons conducting business with the FDA, and thus subject to the applicable administrative regulations.

The burden estimates for this collection of information are based on Agency records and our experience over the past 3 years. By revising the information collection to include additional provisions, we have increased our annual burden estimate by 869 responses and 1,096 hours.

Dated: January 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.
[FR Doc. 2020-00151 Filed: 1/8/2020 8:45 am; Publication Date: 1/9/2020]