Dated: June 6, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–12396 Filed 6–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0134]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Practices and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 12, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0191. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Administrative Practices and Procedures

OMB Control No. 0910–0191—Revision

This information collection helps support implementation of FDA regulations found in part 10 (21 CFR part 10), parts 12 through 16 (21 CFR parts 12 through 16), and part 19 (21 CFR part 19). These regulations are established in accordance with the Administrative Procedures Act (5 U.S.C. subchapter II) and implement administrative practice and procedures to give instructions to those conducting business with FDA. Regulations in 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 parts 12 through 16 cover formal evidentiary, public, and regulatory hearings. The information collection also includes burden associated with waiver requests under § 10.19 (21 CFR 10.19). Unless a waiver, suspension, or modification submitted under § 10.19 is granted by the Commissioner of Food and Drugs, the regulations in part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Because information associated with regulations in parts 12 through 16 is obtained during the conduct of an official administrative action as described under 5 CFR 1320.4, we account only for burden we attribute to initiating the respective actions.

The information collection also includes burden associated with general meeting requests and correspondence submitted to FDA under § 10.65 (21 CFR 10.65), as well as general submissions associated with § 10.115 (21 CFR 10.115) which provides for public participation in the development of Agency guidance documents through requests to our Dockets Management Staff. Most burden attributable to recommendations found in FDA guidance documents is accounted for within information collection request approvals respective to the topic-specific guidance document; however here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3).

The information collection also includes burden that may be associated with the procedural guidance document, ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act'' (September 2019), available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/citizen-petitions-and-petitions-stay-action-subject-section-505q-federal-food-drug-and-cosmetic-act.* The guidance document provides information regarding our current thinking on interpreting section 505(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)) and includes procedural instruction on submitting certain citizen petitions and petitions for stay of FDA action. The guidance document also describes how FDA interprets the provisions of section 505(q) requiring that (1) a petition include a certification and (2) supplemental information or comments on a petition include a verification. It also addresses the relationship between the review of petitions and pending abbreviated new drug applications (ANDAs), 505(b)(2) applications, and 351(k) applications for which a decision on approvability has not yet been made.

In the **Federal Register** of February 7, 2023 (88 FR 7981), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. On our own initiative, however 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 direct them appropriately to determine participation, we have developed web-based templates and questionnaires, and have established dedicated points of contact throughout the Agency. We have therefore revised the estimated burden for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number 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.

Based on submissions to FDA's Division of Dockets Management since our last evaluation of the information collection, we have made adjustments to burden estimates associated with the 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 event, assuming an average burden of 10 minutes for each request. 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.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12523 Filed 6–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0598]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 12, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0154. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226

OMB Control Number 0910–0154—Extension

This information collection supports the implementation of FDA statutory and regulatory requirements that govern current good manufacturing practice (cGMP) for Type A medicated articles. A Type A medicated article is an animal feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency. Section 501 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351), governs current cGMP for drugs, including Type A medicated articles, and these statutory requirements are codified in part 226 (21 CFR part 226).

Manufacturers are required to establish, maintain, and retain records for Type A medicated articles including records to document procedures required under the manufacturing process to assure that proper quality control is maintained under part 226. Type A medicated articles, which are not manufactured in accordance with these regulations, are considered adulterated under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).

Description of Respondents: The respondents to this information collection are manufacturers of Type A medicated articles.

In the **Federal Register** of January 31, 2023 (88 FR 6281), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: