with Medicare program requirements. MOEG reviews submitted data and selected samples from that data to ensure appropriate enrollee access to benefits, services and drugs. Specifically, CMS reviews data to ensure Part D organizations are administering their formulary and transition benefit in accordance with their CMS-approved formulary; CMS reviews coverage requests and appeals to ensure regulatory requirements are followed when enrollees request services; and, if the audited MA organization offers a SNP, MOEG's review evaluates whether the SNP is coordinating care in accordance with CMS requirements. *Form Number:* CMS–10717 (OMB control number: 0938–1395); *Frequency:* Annually; *Affected Public:* Private sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 12,795. (For policy questions regarding this collection contact Caroline Zeman at 410–786–0116 or *caroline.zeman@cms.hhs.gov.*)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–13603 Filed 7–2–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2431]

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

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 August 5, 2026.

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: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, *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.

Administrative Practices and Procedures; Formal Hearings—21 CFR Parts 10, 12–16, and 19

OMB Control Number 0910–0191—Extension

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 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.*

In the **Federal Register** of April 7, 2026 (91 FR 17658), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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.*

FDA estimates the burden of this collection of information 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.	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
10.85—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			4,311		9,440

[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.

Based on submissions to FDA's Division of Dockets Management since our last evaluation of the information collection, we have adjusted burden estimates associated with the individual activities that correspond to the applicable provisions. As a result, the information collection reflects an increase of 3,080 annual burden hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13534 Filed 7–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–0525]

Determination That VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, Injection, 50 units/50 milliliters (1 unit/milliliters) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, injection, 50 units/50 milliliters (mL) (1 unit/mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, injection, 50 units/50 mL (1 unit/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Molly Arndt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6281, Silver Spring, MD 20993–0002, 301–402–6919, *molly.arndt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.