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10.115(f)(3)—submitting draft guidance proposals.	1	1	1	4	4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.

355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, injection, 50 units/50 mL (1 unit/mL), is the subject of NDA 217766, held by Long Grove Pharmaceuticals, LLC, and initially approved on July 11, 2024. VASOPRESSIN IN SODIUM CHLORIDE 0.9% is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

In a letter dated May 9, 2025, Long Grove Pharmaceuticals notified FDA that VASOPRESSIN IN SODIUM CHLORIDE 0.9% (vasopressin) injection, 50 units/50 mL (1 unit/mL), was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Fresenius Kabi USA, LLC submitted a citizen petition dated January 15, 2026 (Docket No. FDA–2026–P–0525), under 21 CFR 10.30, requesting that the Agency determine whether VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, injection, 50 units/50 mL (1 unit/mL), was withdrawn from sale for reasons of safety or effectiveness

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that VASOPRESSIN IN SODIUM CHLORIDE 0.9% (vasopressin) .9%, injection, 50 units/50 mL (1 unit/mL) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, injection, 50 units/50 mL (1 unit/mL), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of VASOPRESSIN IN SODIUM CHLORIDE 0.9% (vasopressin), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list VASOPRESSIN IN SODIUM CHLORIDE 0.9% (vasopressin), injection, 50 units/50 mL (1 unit/mL) in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, injection, 50 units/50 mL (1 unit/mL) may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2915]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

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 0910–0231.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Premarket Approval of Medical Devices

OMB Control Number 0910–0231—Extension

This information collection supports implementation of statutory and regulatory requirements that govern premarket approval of medical devices. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of