## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10439]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by April 8, 2026.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Small Businesses in the Small Business Health Options Program; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152. The Patient Protection and Affordable Care Act (PPACA) expands access to health insurance coverage through improvements to the Medicaid and Children's Health Insurance (CHIP) programs, the establishment of Affordable Insurance Exchanges (Exchanges), and the coordination between Medicaid, CHIP, and Exchanges. Small business employers may participate in and provide health coverage through the Small Business Health Options Program (SHOP), so long as the small business employer obtains a positive eligibility determination from SHOP. Employers will work with SHOP-registered agents/brokers or Issuers offering Qualified Health Plans (QHPs) and Qualified Dental Plans (SADPs), to enroll in SHOP coverage and to select coverage options to offer their employees. SHOP Exchanges became operational on October 1, 2013.

HHS has developed a single, streamlined form that employers use to obtain a SHOP eligibility determination, which is included as an appendix to this Information Collection Request. 45 CFR 155.731 provides more detail about this ''single employer application,'' which is used to determine employer eligibility. Since publication of the last package, no updates have been made in regulation concerning what information should be collected on the single employer application to determine employer eligibility under 45 CFR 155.731. When an employer completes the SHOP Eligibility Determination Form, the form and its results are retained by SHOP for future use, if needed (*e.g.,* reconciliation with issuer records, SHOP employer appeals, etc.). *Form Number:* CMS–10439 (OMB control number: 0938–1193); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 2,100; *Number of Responses:* 2,100; *Total Annual Hours:* 336. (For questions regarding this collection, contact Mary Guy at 410–786–2772).

**William N. Parham III,**

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

[FR Doc. 2026–04518 Filed 3–6–26; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–1302]**

### Aspen Global Inc. c/o Lachman Consultant Services, Inc., et al.; Withdrawal of Approval of 46 New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 46 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of April 8, 2026.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 000552 | Liquaemin Sodium (heparin sodium) injectable, 1,000 units/milliliter (mL), 5,000 units/mL, 10,000 units/mL, 20,000 units/mL, and 40,000 units/mL.<br>Liquaemin Sodium Preservative Free (heparin sodium) injectable, 1,000 units/mL, 5,000 units/mL, and 10,000 units/mL.<br>Liquaemin Lock Flush (heparin sodium) injectable, 100 units/mL.<br>Heparin Sodium (heparin sodium) injectable, 1,000 units/mL, 5,000 units/mL, and 10,000 units/mL. | Aspen Global Inc. c/o Lachman Consultant Services, Inc., 1600 Stewart Ave., Westbury, NY 11590. |
| NDA 008370 | Bentyl (dicyclomine hydrochloride (HCl)) injectable, 10 milligrams (mg)/mL.<br>Bentyl Preservative Free (dicyclomine HCl) injectable, 10 mg/mL. | AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064. |
| NDA 008943 | Diamox (acetazolamide) tablets, 125 mg and 250 mg | Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Parkway, West Chester, PA 19380. |
| NDA 011600 | Triamcinolone Acetonide (triamcinolone acetonide) ointment, 0.025%, and 0.1%. | Extrovis AG c/o Masuu Global Solutions LLC, 2255 Glades Rd., Suite 324A, Boca Raton, FL 33431. |
| NDA 012250 | Carbocaine (mepivacaine HCl) injectable, 1%, 1.5%, and 2% | Hospira, Inc., a Pfizer company, 275 North Field Dr., Lake Forest, IL 60045. |
| NDA 012623 | Flagyl (metronidazole) tablets, 250 mg and 500 mg | Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001. |
| NDA 017498 | Micronase (glyburide) tablets, 1.25 mg, 2.5 mg, and 5 mg | Do. |
| NDA 017630 | Sodium Iodide I-123 (sodium iodide I-123) capsules, 100 microcurie (μCi), 200 μCi, and solution, 2 millicurie (mCi)/mL. | GE HealthCare, 3350 North Ridge Ave., Arlington Heights, IL 60004. |
| NDA 017741 | Florone (diflorasone diacetate) cream, 0.05% | Pfizer Inc. |
| NDA 017802 | Lo/Ovral-28 (ethinyl estradiol; norgestrel) tablets, 0.03 mg; 0.3 mg | Wyeth Pharmaceuticals LLC c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001. |
| NDA 017948 | Norminest Fe (tablets, ethinyl estradiol; norethindrone, 0.035 mg; 0.5 mg, and tablets, ferrous fumarate, 75 mg). | Pfizer Inc. |
| NDA 018647 | Corzide (bendroflumethiazide; nadolol) tablets, 5 mg; 40 mg and 5 mg; 80 mg. | King Pharmaceuticals LLC, c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001. |
| NDA 018799 | Protopam (pralidoxime chloride) injectable, 300 mg/mL | Baxter Healthcare Corp., 25212 W Illinois Route 120, Round Lake, IL 60073. |
| NDA 018926 | Norquest Fe (tablets, ethinyl estradiol; norethindrone, 0.035 mg; 1 mg, and tablets, ferrous fumarate, 75 mg). | Pfizer Inc. |
| NDA 018947 | Sodium Lactate in Plastic Container (sodium lactate), injectable, 50 milliequivalents (mEq)/mL. | Hospira, Inc. |
| NDA 019190 | Triphasil-28 (ethinyl estradiol; levonorgestrel) tablets, 0.03 mg; 0.05 mg, tablets, 0.04 mg; 0.075 mg, and tablets, 0.03 mg; 0.125 mg. | Wyeth Pharmaceuticals c/o Pfizer Inc. |
| NDA 019192 | Triphasil-21 (ethinyl estradiol; levonorgestrel) tablets, 0.03 mg; 0.05 mg, tablets, 0.04 mg; 0.075 mg, and tablets, 0.03 mg; 0.125 mg. | Do. |
| NDA 019885 | Accupril (quinapril HCl) tablets, equivalent to (EQ) 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base. | Pfizer Inc. |
| NDA 019941 | Emla (lidocaine; prilocaine) cream, 2.5%; 2.5% | Teva Branded Pharmaceutical Products R&D Inc. |
| NDA 019966 | Temovate (clobetasol propionate) solution, 0.05% | Fougera Pharmaceuticals Inc., c/o Sandoz (a subsidiary of Novartis), 100 College Rd., West, Princeton, NJ 08540. |
| NDA 020051 | Glynase (glyburide) tablets, 1.5 mg, 3 mg, 4.5 mg, and 6 mg | Pfizer Inc. |
| NDA 020125 | Accuretic (hydrochlorothiazide; quinapril HCl) tablets, 12.5 mg; EQ 10 mg base, 12.5 mg; EQ 20 mg base, and 25 mg; EQ 20 mg base. | Do. |
| NDA 020430 | Orgaran (danaparaoid sodium) injectable, 750 units/0.6 mL | Aspen Global Inc. c/o Lachman Consultant Services, Inc. |
| NDA 020682 | Glyset (miglitol) tablets, 25 mg, 50 mg, and 100 mg | Pfizer Inc. |
| NDA 020859 | Sonata (zaleplon) capsules, 5 mg and 10 mg | Do. |
| NDA 020862 | Hectorol (doxercalciferol) capsules, 0.5 microgram (mcg), 1 mcg, and 2.5 mcg. | Genzyme Corp., a Sanofi company, 450 Water St., Cambridge, MA 02141. |
| NDA 020868 | Flagyl ER (metronidazole) extended-release tablet, 750 mg | Pfizer Inc. |
| NDA 021350 | Triglide (fenofibrate) tablets, 50 mg and 160 mg | Jagotec AG c/o. ICON, 731 Arbor Way, Suite 100, Blue Bell, PA 19422. |
| NDA 021520 | Symbyax (fluoxetine HCl; olanzapine) capsules, EQ 25 mg base; EQ 3 mg base, EQ 25 mg base; EQ 6 mg base, EQ 25 mg base; EQ 12 mg base, EQ 50 mg base; EQ 6 mg base, and EQ 50 mg base; EQ 12 mg base. | Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285. |
| NDA 021688 | Sensipar (cinacalcet HCl) tablets, EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base. | Amgen, Inc., 1 Amgen Center Dr., Thousand Oaks, CA 91320–1799. |
| NDA 022200 | Bydureon (exenatide synthetic) extended-release injection for suspension, 2 mg/vial.<br>Bydureon Pen (exenatide synthetic) extended-release injection for suspension, 2 mg. | AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803. |
| NDA 050168 | Cortisporin (bacitracin zinc; hydrocortisone; neomycin sulfate; polymyxin B sulfate) ointment, 400 units/gram (g); 1%; EQ 3.5 mg base/g; 5,000 units/g. | Monarch Pharmaceuticals, LLC c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001. |
| NDA 050218 | Cortisporin (hydrocortisone acetate; neomycin sulfate; polymyxin B sulfate) cream, 0.5%; EQ 3.5 mg base/g; 10,000 units/g. | Do. |
| NDA 050420 | Rifadin (rifampin) capsules, 150 mg and 300 mg | Sanofi-Aventis U.S. LLC, a Sanofi company, 55 Corporate Dr., Bridgewater, NJ 08807. |
| NDA 050479 | Cortisporin (hydrocortisone; neomycin sulfate; polymyxin B sulfate) otic solution/drops, 1%; EQ 3.5 mg base/mL; 10,000 units/mL. | Monarch Pharmaceuticals, LLC c/o Pfizer Inc. |

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 050533 | Vibra-Tabs (doxycycline hyclate) tablet, EQ 100 mg base | Pfizer Inc. |
| NDA 050661 | Idamycin (idarubicin HCL) powder, 5 mg/vial, 10 mg/vial, and 20 mg/vial. | Pfizer Inc. |
| NDA 050705 | Rifater (isoniazid; pyrazinamide; rifamin) tablets, 50 mg; 300 mg; 120 mg. | Sanofi-Aventis U.S. LLC, a Sanofi company, 100 Morris St., Morristown, NJ 07960. |
| NDA 201657 | Paricalcitol (paricalcitol) solution, 0.002 mg/mL (0.002 mg/mL), 0.005 mg/mL (0.005 mg/mL), and 0.01 mg/2 mL (0.005 mg/mL). | Hospira, Inc. |
| NDA 204016 | Zoledronic Acid (zoledronic acid) solution, EQ 4 mg base/100 mL (EQ 0.04 mg base/mL). | Do. |
| NDA 204300 | Vazculep (phenylephrine HCL) solution, 10 mg/mL (10 mg/mL), 50 mg/5 mL (10 mg/mL), and 100 mg/10 mL (10 mg/mL). | Exela Pharma Sciences, LLC, P.O. Box 818, 1245 Blowing Rock Blvd., Lenoir, NC 28645. |
| NDA 207202 | Abilify MyCite Kit (aripiprazole) tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg. | Otsuka Pharmaceutical Co., Ltd., c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 208500. |
| NDA 208614 | Doxercalciferol (doxercalciferol) injectable, 4 mcg/2 mL (2 mcg/mL) and 10 mcg/5 mL (2 mcg/mL). | Hospira, Inc. |
| NDA 209210 | Bydureon BCise (exenatide synthetic) extended-release injection suspension, 2 mg/0.85 mL. | AstraZeneca Pharmaceuticals LP. |
| NDA 209269 | Minolira (minocycline HCl) extended-release tablets, EQ 105 mg base and EQ 135 mg base. | EPI Health, LLC, 174 Meeting St., Suite 200, Charleston, SC 29401. |
| NDA 209607 | Azedra (iobenguane I-131) solution, 15 mCi/mL | Progenics Pharmaceuticals, Inc., a Lantheus company, 201 Burlington Rd., South Building, Bedford, MA 01730. |

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of April 8, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on April 8, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–04546 Filed 3–6–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–1867]**

### Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 220359, for Camizestrant Tablets; Supplemental New Drug Application (sNDA) 218197/S–004, for Truqap (Capivasertib) Tablets

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on April 30, 2026, from 8:00 a.m. to 5:00 p.m. Eastern Time.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2026–N–1867. The docket will close on April 29, 2026. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 29, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before April 16, 2026, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

*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