effectiveness. Records required under 21 CFR part 820 may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

The overall burden increase of approximately 244% for reporting and 212% for recordkeeping represents a substantial change in the estimated regulatory burden for the PMA program. The increases are driven primarily by changes in estimated submission frequency rather than changes in the number of regulated entities or per-response burden estimates. The most significant factor is the dramatic increase in responses per respondent across multiple categories, particularly for 30-day notices (15× increase), PMA amendments (4× increase), pediatric information (6× increase), and eSTAR setup (6× increase). These changes suggest that the current estimates better capture the actual submission patterns and regulatory interactions that occur throughout the lifecycle of approved medical devices, reflecting more frequent modifications, updates, and communications between industry and FDA than were captured in the previous estimates based on 2019–2021 data.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13519 Filed 7–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6809]

Endo Operations Limited, et al.; Withdrawal of Approval of 34 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 34 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 5, 2026.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, 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 007337	Percodan (aspirin; oxycodone hydrochloride (HCl)) Tablets, 325 milligrams (mg); 4.8355 mg. Percodan (aspirin; oxycodone HCl; oxycodone terephthalate) Tablets, 325 mg; 4.5 mg; 0.38 mg. Percodan-Demi (aspirin; oxycodone HCl; oxycodone terephthalate) Tablets, 325 mg; 4.5 mg; 0.19 mg.	Endo Operations Limited c/o Endo USA, Inc., 9 Great Valley Parkway, Malvern, PA 19355.
NDA 017376	Septra (sulfamethoxazole; trimethoprim) Tablets, 80 mg; 400 mg. Septra DS (sulfamethoxazole; trimethoprim) Tablets, 160 mg; 800 mg.	Monarch Pharmaceuticals, LLC c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 017994	Psorcon E (diflorasone diacetate) Ointment, 0.05%	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 018701	Haldol (haloperidol decanoate) Injectable, equivalent to (EQ) 50 mg base/milliliter (mL) and EQ 100 mg base/mL.	Janssen Pharmaceuticals, Inc., c/o Janssen Research and Development, 920 U.S. Highway 202, P.O. Box 300, Raritan NJ 08869–0602.
NDA 019151	Rythmol (propafenone HCl) Tablets, 150 mg, 225 mg, and 300 mg.	GlaxoSmithKline LLC, 2929 Walnut St., Suite 1700, Philadelphia, PA 19104.
NDA 019260	Psorcon (diflorasone diacetate) Ointment, 0.05%	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 019795	Condylox (podofilox) Solution, 0.5%	Teva Branded Pharmaceutical Products R&D LLC, 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 020140	Fusilev (levoleucovorin calcium) Powder, EQ 50 mg base/vial, EQ 175 mg base/17.5 mL (EQ 10 mg base/mL), and EQ 250 mg base/25 mL (EQ 10 mg base/mL).	Acrotech Biopharma Inc., 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
NDA 020337	Temovate (clobetasol propionate) Gel, 0.05%	Fougera Pharmaceuticals LLC, 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747.
NDA 020490	Alphagan (brimonidine tartrate) Solution/Drops, 0.5%	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623–9534.
NDA 020579	Flomax (tamsulosin HCl) Capsule, 0.4 mg	Sanofi-Aventis U.S. LLC, 100 Morris Ave., Morristown, NJ 07960.
NDA 020657	Sporanox (itraconazole) oral solution, 10 mg/ml	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 021040	Prefest (estradiol 1mg and estradiol; norgestimate 1 mg; 0.09 mg), Tablets.	Teva Women's Health, Inc., 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 021292	Euthyrox (levothyroxine sodium) Tablets, 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.1 mg, 0.112 mg, 0.125 mg, 0.137 mg, 0.15 mg, 0.175 mg, 0.2 mg, and 0.3 mg.	EMD Serono, Inc. c/o ICON Clinical Research LLC, 731 Arbor Way, Suite 100, Blue Bell, PA 19422.
NDA 021416	Rythmol SR (propafenone HCl) Extended-Release Capsules, 225 mg, 325 mg, and 425 mg..	GlaxoSmithKline LLC, 2929 Walnut St., Suite 1700, Philadelphia, PA 19104.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
NDA 021481	Fuzeon (enfuviritide) Injectable, 90 mg/vial.	Hoffmann-La Roche Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.
NDA 021548	Lexivia (fosamprenavir calcium) Tablet, EQ 700 mg base.	Viiv Healthcare Co., 410 Blackwell St., Durham, NC 27701.
NDA 021606	Zemplar (paricalcitol) Capsules, 1 microgram (mcg), 2 mcg, and 4 mcg.	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 021656	TriCor (fenofibrate) Tablets, 48 mg and 145 mg	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 021779	Ventavis (iloprost) Solution, 10 mcg/mL (10 mcg/mL), 20 mcg/2 mL (10 mcg/mL) and 20 mcg/mL (20 mcg/mL).	Actelion Pharmaceuticals US, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 021947	Fentora (fentanyl citrate) Tablets, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base.	Cephalon LLC, a wholly owned subsidiary of Teva Pharmaceuticals USA Inc., 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 022116	Lexivia (fosamprenavir calcium) Suspension, EQ 50 mg base/mL.	Viiv Healthcare Co., 410 Blackwell St., Durham, NC 27701.
NDA 022206	Rapaflo (silodosin) Capsules, 4 mg and 8 mg	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 022224	Trilipix (choline fenofibrate) Delayed-Release Capsules, EQ 45 mg fenofibric acid and EQ 135 mg fenofibric acid.	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 022511	Vimovo (esomeprazole magnesium; naproxen) Delayed-Release Tablets, EQ 20 mg base; 375 mg, and EQ 20 mg base; 500 mg.	Horizon Therapeutics USA, Inc., 1 Horizon Way, Deerfield, IL 60015.
NDA 050467	Doxorubicin Hydrochloride (doxorubicin HCl) Injectable, 10 mg/vial, 20 mg/vial, 50 mg/vial, and 150 mg/vial.	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 201194	Oxycodone Hydrocholoride (oxycodone HCl) Solution, 5 mg/5 mL.	VistaPharm, LLC, 20 Waterview Blvd., Suite 303, Parsippany, NJ 07054.
NDA 202020	Rayos (prednisone) Delayed-Release Tablets, 1 mg, 2 mg, and 5 mg.	Horizon Therapeutics USA, Inc., 1 Horizon Way, Deerfield, IL 60015.
NDA 204623	Pennsaid (diclofenac sodium) Solution, 2%	Horizon Therapeutics Ireland DAC c/o Horizon Therapeutics USA, Inc., 1 Horizon Way, Deerfield, IL 60015.
NDA 204803	Posimir (bupivacaine) Solution, 660 mg/5 mL (132 mg/mL) ..	Innocoll Pharmaceuticals Limited c/o Allucent, 2000 Centregreen Way, Suite 300, Cary, NC 27513.
NDA 206030	Carnexiv (carbamazepine) Solution, 200 mg/20 mL (10 mg/mL).	Lundbeck Pharmaceuticals LLC, 6 Pkwy. North, Suite 400, Deerfield, IL 60015.
NDA 209128	Dsuvia (sufentanil citrate) Tablet, EQ 0.03 mg base	Vertical Pharmaceuticals, LLC, 1880 McFarland Pkwy., Suite 110B, Alpharetta, GA 30005.
NDA 209511	Xaracoll (bupivacaine HCl) Implant, 100 mg	Innocoll Pharmaceuticals Limited c/o Allucent, 2000 Centregreen Way, Suite 300, Cary, NC 27513.
NDA 211280	Reyvow (lasmiditan succinate) Tablets, EQ 50 mg base, EQ 100 mg base, and EQ 200 mg base.	Eli Lilly and Company, Lilly Corporate Center, Drop Code 2543, Indianapolis, IN 46285.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of August 5, 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 August 5, 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. 2026–13616 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–N–6667]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biologics License Applications, Procedures and Requirements

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 activities associated with Biologics License Applications, Procedures and Requirements.

DATES: Either electronic or written comments on the collection of information must be submitted by September 4, 2026.

ADDRESSES: You may submit comments as follows. 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 September 4, 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.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.