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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

[FR Doc. 2026–13492 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–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

illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act (21 U.S.C. 360e) in order to obtain marketing approval. Please note that PMA requirements apply differently to pre-amendments devices, post amendments devices, and transitional class III devices and some Class III pre-amendment devices may require a Class III 510(k). See the PMA Historical Background Web page at *https://www.fda.gov/medical-devices/premarket-approval-pma/pma-historical-background* for additional information. Section 515A of the FD&C Act (21 U.S.C. 360e–1) governs pediatric uses of devices.

The PMA is the most stringent type of device marketing application required by FDA. Applicants must receive FDA approval of a PMA application prior to marketing the device. PMA approval is based on a determination that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). Respondents to the information collection are PMA applicants, or persons who own the rights, or otherwise have authorized access, to the data and other information to be submitted in support of FDA approval. This person may be an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. The applicant is often the inventor/developer and ultimately the manufacturer. A Class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (21 U.S.C. 351(f)) and may not be marketed.

FDA regulations in part 814 (21 CFR part 814) implement section 515 and 515A of the FD&C Act and establish procedures for the premarket approval of medical devices intended for human use, including the submission of information concerning use in pediatric patients. Regulations in part 814, subpart A (§§ 814.1 to 814.19) set forth general provisions pertaining to the confidentiality of data and information submitted to FDA in a PMA, research conducted outside the United States, service of orders, and product development protocols. Provisions in part 814, subparts B and C (§§ 814.20 to 814.47) establish format and content elements that must be included in an application, explain submission, and review schedules, and address the withdrawal and temporary suspension of a PMA. post approval requirements, including reports required under 21 CFR part 803 (medical device reporting), are covered in regulations in part 814, subpart E (§§ 814.80 to 814.84). Burden attributable to information collection associated with regulations in part 814, subpart H (§§ 814.100 to 814.126) pertaining to Humanitarian Use Devices is currently approved in OMB control number 0910–0332.

For operational efficiency, we are revising the information collection to include burden that may be associated with recommendations found in the Agency guidance document entitled, ''Providing Information about Pediatric Uses of Medical Devices'' (May 2014), currently approved in OMB control number 0910–0748. The guidance document describes how to compile and submit the readily available pediatric use information required under section 515A of the FD&C Act. The guidance document is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-information-about-pediatric-uses-medical-devices.*

Relatedly, we are revising the information collection to include burden that may be associated with the submission of information on pediatric use of medical devices under section 515A of the FD&C Act, also currently approved in OMB control number 0910–0748. Section 515A(a) of the FD&C Act requires applicants who submit information to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. This information allows FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

We are also revising the information collection to include burden applicable to implementing requirements under section 402(j)(5)(B) of the Public Health Service (PHS) Act (42 U.S.C. 282(j)(5)(B)), and set forth in regulations at 42 CFR part 11 (see 81 FR 64982, September 21, 2016). Specifically, applications under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act, must be accompanied by a certification. Where available, such certification must include the appropriate National Clinical Trial numbers. We have developed Form FDA 3674 (''Certification of Compliance Under 42 U.S.C. 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (includes instructions''), available at *https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/clinical-trial-forms* for respondents to submit the requisite information.

Respondents can make single submissions in an electronic format that includes eCopies, submissions submitted on CD, DVD, or flash drive and mailed to FDA and eSubmissions, submissions created using an electronic submission template (*e.g.,* ''electronic Submission Template and Resource'' (eSTAR)). Consistent with our authority in section 745A(b) of the FD&C Act (21 U.S.C. 379k–1(b)), and performance goals found in our current Medical Device User Fee Amendments Commitment Letter, we developed eSTAR for use through the Center for Devices and Radiological Health Customer Collaboration Portal. We use eSTAR as a tool to facilitate the preparation of submissions in electronic format (available on FDA's website at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program* and identified as Form FDA 4062 ''Electronic Submission Template and Resource (eSTAR)'' (for Non-In Vitro Diagnostic submissions) and form FDA 4078 ''Electronic Submission Template and Resource (eSTAR)'' (for In Vitro Diagnostic submissions)). We believe respondents' use of eSTAR will significantly reduce burden attendant to application submissions by providing a uniform format for requisite elements and by enhancing user interface through the use of modernized technology.

In the **Federal Register** of April 10, 2026 (91 FR 18468), 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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity/21 CFR or FD&C Act section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Premarket Approval Submissions ("traditional" and eSTAR preparation; eCopy submission):					
21 CFR Part 814, Premarket Approval of Medical Devices					
Subpart A—General:					
Research conducted outside the United States (814.15(b)).	18	1	18	2	36
Subpart B—Premarket Approval Application (PMA)					
PMA application (814.20)	61	1	61	654.6 (654 hours, 38 minutes)	39,931
Information on clinical investigations conducted outside the United States (814.20(b)(6)(ii)(C)).	18	1	18	0.5 (30 minutes)	9
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e)).	1,125	4	4,500	167	751,500
PMA supplements (814.39(a))	598	3	1,794	0.983 (59.11 minutes)	1,764
Special PMA supplement—changes being affected (814.39(d)).	85	2	170	6	1,020
30-day notice (814.39(f))	1,499	15	22,485	16	359,760
Subtotal subpart B					1,153,984
Subpart C—FDA Action on a PMA:					
Panel of experts request (814.42 and 515(c)(3) of the FD&C Act).	4	1	4	30	120
Subpart E—Postapproval Requirements:					
Postapproval requirements (814.82(a)(9))	14	1	14	135	1890
Periodic reports (814.84(b))	860	2	1,720	10	17,200
Subtotal subpart E					19,090
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance "Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"					
Certification to accompany PMA submissions (Form FDA 3674).	61	1	61	0.75 (45 minutes)	46
FD&C Act section 515A Pediatric Uses of Devices and FDA Guidance "Providing Information about Pediatric Uses of Medical Devices":					
Pediatric information in a PMA, PDP, or PMA supplement	659	6	3,954	2.10 (2 hours, 6 minutes)	8,303
Pediatric use information outside approved indication	6	1	6	0.5 (30 minutes)	3
Subtotal					8,306
Premarket Approval Submissions (eSTAR preparation):					
eSTAR setup	1,529	6	9,174	0.08 (5 minutes)	734
Total					1,182,316

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on the annual rate of receipt of PMA submissions, including PDPs and PMA supplements, for fiscal years 2022 through 2024 and our expectation of submissions to come in the next few years. We also account for referrals of PMAs to a panel for review, as provided for under § 814.44(a). FDA may refer the PMA to a panel on its own initiative, and will do so upon request of an applicant, unless FDA determines that the application substantially duplicates information previously reviewed by a panel. We have adjusted our figures to reflect an overall decrease, which we attribute to respondents' use of modernized submission technologies including eSTAR. At the same time, we include in our estimate an initial burden attributable to respondents who need to set up an eSTAR account for the first time.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Number of recordkeepers	Number of recordkeepers	Number of recordkeepers	Number of recordkeepers	Average burden per recordkeeping	Total hours
860	860	860	860	17	29,240

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The regulations require the maintenance of records, which are used to trace patients, and the organization and indexing of records into identifiable files to ensure a device's continued safety and effectiveness. These records are required of all applicants who have an approved PMA. Currently there are 860 active PMAs that could be subject to these requirements, based on FDA data, and approximately 33 new PMAs are approved each year. We estimate our annual recordkeeping burden based on an average of 860 PMA holders. The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and

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.