FDA has become aware that the drug products listed in the table are no longer being marketed.

TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 009165	DELATESTRYL	Testosterone Enanthate	200 Milligrams (mg)/Milliliter (mL).	Injectable; Injection	Endo Pharmaceuticals Inc.
NDA 011145	DIURIL	Chlorothiazide Sodium	Equivalent to (EQ) 500 mg base/Vial.	Injectable; Injection	Rising Pharma Holdings Inc.
NDA 013217	SKELAXIN	Metaxalone	800 mg	Tablet; Oral	King Pharmaceuticals Research and Development LLC, a subsidiary of Pfizer Inc.
NDA 017710	NALFON	Fenoprofen Calcium	EQ 600 mg Base	Tablet; Oral	Dista Products Co., a division of Eli Lilly and Co.
NDA 018716	TRANDATE	Labetalol Hydrochloride	100 mg; 200 mg; 300 mg	Tablet; Oral	Alvogen Inc.
NDA 018827	LOTRISONE	Betamethasone Dipropionate; Clotrimazole.	EQ 0.05% Base; 1%	Cream; Topical	Organon LLC, a subsidiary of Organon and Co.
NDA 020080	IMITREX	Sumatriptan Succinate	EQ 6 mg Base/0.5 mL (EQ 12 mg Base/mL).	Injectable; Subcutaneous.	GlaxoSmithKline.
NDA 020617	PYTEST KIT	Urea, C–14	1 mCi	Capsule; Oral	Avent Inc.
NDA 020763	AMERGE	Naratriptan Hydrochloride	EQ 1 mg Base; EQ 2.5 mg Base.	Tablet; Oral	GlaxoSmithKline.
NDA 020897	DITROPAN XL	Oxybutynin Chloride	5 mg; 10 mg	Tablet, Extended Release; Oral.	Janssen Pharmaceuticals Inc.
NDA 020918	GLUCAGEN	Glucagon Hydrochloride	EQ 1 mg Base/Vial	Injectable; Injection	Novo Nordisk Pharmaceuticals Inc.
NDA 020928	GLUCAGON	Glucagon	1 mg/Vial	Injectable; Injection	Eli Lilly and Co.
NDA 021615	RAZADYNE ER	Galantamine Hydrobromide	EQ 8 mg Base; EQ 16 mg Base; EQ 24 mg Base.	Capsule, Extended Release; Oral.	Janssen Pharmaceuticals Inc.
NDA 021627	NAMENDA	Memantine Hydrochloride	2 mg/mL	Solution; Oral	Allergan Sales LLC.
NDA 021652	EPZICOM	Abacavir Sulfate; Lamivudine	EQ 600 mg Base, 300 mg	Tablet; Oral	ViiV Healthcare Co.
NDA 021743	TARCEVA	Erlotinib Hydrochloride	EQ 25 mg Base; EQ 100 mg Base; EQ 150 mg Base.	Tablet; Oral	OSI Pharmaceuticals LLC.
NDA 021892	OSMOPREP	Sodium Phosphate, Dibasic, Anhydrous; Sodium Phosphate, Monobasic, Monohydrate.	0.398 grams (g)m; 1.102 (g)	Tablet; Oral	Salix Pharmaceuticals Inc.
NDA 022013	OLUX E	Clobetasol Propionate	0.05%	Aerosol, Foam; Topical	Mylan Pharmaceuticals Inc.
NDA 022204	GELNIQUE	Oxybutynin Chloride	10% (100 mg/Packet)	Gel; Transdermal	Abbvie Inc.
NDA 022525	NAMENDA XR	Memantine Hydrochloride	7 mg	Capsule, Extended Release; Oral.	Abbvie Inc.
NDA 050168	CORTISPORIN	Bacitracin Zinc; Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate.	400 units/g 1%, EQ 3.5 mg Base/g, 5,000 units/g.	Ointment; Topical	Monarch Pharmaceuticals LLC.
NDA 050218	CORTISPORIN	Hydrocortisone Acetate; Neomycin Sulfate; Polymyxin B Sulfate.	0.5%, EQ 3.5 mg Base/g, 10,000 units/g.	Cream; Topical	Monarch Pharmaceuticals LLC.
NDA 050278	ACHROMYCIN V	Tetracycline Hydrochloride	250 mg; 500 mg	Capsule; Oral	Avet Pharmaceuticals Inc.
NDA 050578	FORTAZ	Ceftazidime	500 mg/Vial; 1 g/Vial; 2 g/Vial; 6 g/Vial.	Injectable; Injection	PAI Holdings LLC DBA Pharmaceutical Associates Inc.
NDA 050679	MAXIPIME	Cefepime Hydrochloride	EQ 500 mg Base/Vial; EQ 1 g Base/Vial; EQ 2 g Base/Vial.	Injectable; Injection	Hospira Inc.
NDA 202543	LEVETIRACETAM IN SODIUM CHLORIDE.	Levetiracetam	250 mg/50 mL (5 mg/mL)	Injectable; Intravenous	HQ Specialty Pharma Corp.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17649 Filed 8–7–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2422]

Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Reopening the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening the comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is reopening the comment period for the proposed administrative order (proposed order) entitled ''Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use'', announced in the **Federal Register** of June 14, 2024. We are taking this action due to technical difficulties with the OTC Monographs@FDA portal. Because comments cannot be submitted to the OTC Monographs@FDA portal at this time, submit comments on proposed order (OTC000035) to the Federal eRulemaking portal (Docket No. FDA–2024–N–2422).

DATES: FDA is reopening the comment period on proposed order (OTC000035) announced in the **Federal Register** of June 14, 2024 (89 FR 50593). Electronic comments or written comments must be submitted by September 27, 2024.

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 27, 2024. 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.* Other than using the Federal eRulemaking Portal to submit comments (instead of the OTC Monographs@FDA portal), follow the instructions for submitting comments on the proposed order (OTC000035) available in the OTCMonographs@FDA portal at *https://dps.fda.gov/omuf.*

FOR FURTHER INFORMATION CONTACT: Helen Lee, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0138.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 14, 2024 (89 FR 50593), FDA announced the availability of proposed order (OTC000035) entitled ''Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use.'' The proposed administrative order (proposed order), if finalized, will amend the requirements for internal analgesic, antipyretic, and antirheumatic drug products for over-the-counter (OTC) human use, as currently described in Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (OTC Monograph M013).[1]

Interested persons were originally given until July 29, 2024, to comment on the proposed order (OTC000035) via the OTC Monographs@FDA portal. However, as of June 14, 2024, technical difficulties prevented the electronic submission of comments through the OTC Monographs@FDA portal. Therefore, we are reopening the comment period for the proposed order (OTC000035) and are instead accepting comments through the Federal eRulemaking Portal. Accordingly, submit comments on the proposed order (OTC000035) electronically using Docket No. FDA–2024–N–2422 in the Federal eRulemaking Portal at *https://www.regulations.gov.* The reopened comment period will close on September 27, 2024.

The proposed order (OTC000035) remains available in the OTC Monographs@FDA portal at *https://dps.fda.gov/omuf.* Other than using the Federal eRulemaking Portal to submit comments (instead of the OTC Monographs@FDA portal), follow the instructions for submitting comments on the proposed order (OTC000035) available in the OTC Monographs@FDA portal at *https://dps.fda.gov/omuf.* The proposed order contains general instructions for commenting, which otherwise remain applicable.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17645 Filed 8–7–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Advisory Committee; Blood Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Blood Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2026, expiration date.

DATES: Authority for the Blood Products Advisory Committee will expire on May 13, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–731–3544, *Christina.Vert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Blood Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which FDA has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program, which provides the scientific support for regulating these agents.

The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends

[1] OTC Monograph M013 is currently set forth in the Final Administrative Order OTC000027. We note that at 89 FR 50593 at 50594, the notice of availability for the proposed order to amend OTC Monograph M013 erroneously referred to ''Final Administrative Order OTC000027'' as ''Final Administrative Order OTC000035.''