meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting presentations will also be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The online presentation of materials will include slide presentations with audio and video components in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before August 29, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately between 1:45 p.m. to 2:45 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before August 21, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by August 22, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17642 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3531]

Determination That DELATESTRYL (Testosterone Enanthate) Injection, 200 Milligrams/Milliliter, and Other Drug Products Were 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 the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

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.