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That DELATESTRYL (Testosterone Enanthate) Injection, 200 Milligrams/Milliliter, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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.

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