4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4319]

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VERSENATE (Edetate Calcium Disodium) Injection, 200 Milligrams Per Milliliter, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is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

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 008922	CALCIUM DISODIUM VERSENATE	Edetate Calcium Disodium	200 Milligrams (mg)/Milliliter (mL)	Injectable; Injection	Bausch Health US, LLC
NDA 011722	TENUATE	Diethylpropion Hydrochloride	25 mg	Tablet; Oral	Nostrum Labs., Inc.
NDA 012546	TENUATE DOSPAN	Diethylpropion Hydrochloride	75 mg	Tablets, Extended-Release; Oral	Do.
NDA 019117	FLUOCINONIDE	Fluocinonide	0.05%	Cream; Topical	Taro Pharms. U.S.A., Inc.
NDA 019796	ELOCON	Mometasone Furoate	0.1%	Lotion; Topical	Organon, LLC
NDA 020489	ANDRODERM	Testosterone	2 mg/24 hours; 4 mg/24 hours	Film, Extended Release; Transdermal	AbbVie Inc.
NDA 020884	AGGRENOX	Aspirin; Dipyridamole	25 mg; 200 mg	Capsule, Extended Release; Oral	Boehringer Ingelheim Pharms., Inc.
NDA 020903	REBETOL	Ribavirin	200 mg	Capsule; Oral	Merck Sharp and Dohme Corp.
NDA 020907	ACTIVELLA	Estradiol; Norethindrone Acetate	0.5 mg; 0.1 mg	Tablet; Oral	Amneal Pharms., LLC
NDA 020949	ACCUNEB	Albuterol Sulfate	Equivalent to (EQ) 0.021% Base; EQ 0.042% Base	Solution; Inhalation	Mylan Specialty LP
NDA 021022	PENLAC	Ciclopirox	8%	Solution; Topical	Valeant International Bermuda
NDA 021449	HEPSERA	Adefovir Dipivoxil	10 mg	Tablet; Oral	Gilead Sciences, Inc.
NDA 022052	ZYFLO CR	Zileuton	600 mg	Tablet, Extended Release; Oral	Chiesi USA, Inc.
NDA 022511	VIMOVO	Esomeprazole Magnesium; Naproxen	EQ 20 mg Base; 375 mg; EQ 20 mg Base; 500 mg	Tablet, Delayed Release; Oral	Horizon Medicines LLC
NDA 022569	LAZANDA	Fentanyl Citrate	EQ 0.1mg Base; EQ 0.3 mg Base; EQ 0.4 mg Base	Spray, Metered; Nasal	BTcP Pharma, LLC
NDA 202788	SUBSYS	Fentanyl	0.1 mg; 0.2 mg; 0.4 mg; 0.6 mg; 0.8 mg; 1.2 mg; 1.6 mg	Spray; Sublingual	Do.
NDA 213645	DAPZURA RT	Daptomycin	500 mg/Vial	Powder; Intravenous	Baxter Healthcare 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: October 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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