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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3894]

Determination That TENSILON and TENSILON Preservative Free (Edrophonium Chloride) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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. 6207, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as

the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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 in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 007959	TENSILON and TENSILON Preservative Free (edrophonium chloride) Injectable; Intravenous, 10 milligrams/milliliter (mg/mL).	IGI Laboratories, Inc., 105 Lincoln Ave., Buena, NJ 08310

Application No.	Drug	Applicant
NDA 013416	NORGESIC and NORGESIC FORTE (aspirin, caffeine, orphenadrine citrate) Tablet; Oral,385 mg/30 mg/25 mg; 770 mg/60 mg/50 mg.	Medicis Pharmaceuticals, Division of Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
NDA 018225	BUMEX (bumetanide) Tablet; Oral, 0.5 mg; 1 mg; 2 mg.	Validus Pharmaceuticals, LLC, 119 Cherry Hill Rd., Suite 310, Parsippany, NJ 07054
NDA 018343	CAPOTEN (captopril) Tablet; Oral, 12.5 mg; 25 mg; 50 mg; 100 mg.	Par Pharmaceutical Inc., 1 Ram Ridge Rd., Chestnut Ridge, NY 10977
NDA 019322	TEMOVATE (clobetasol propionate) Cream; Topical, 0.05%.	Fougera Pharmaceuticals Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747
NDA 020337	TEMOVATE (clobetasol propionate) Gel; Topical, 0.05%.	Do.
NDA 020340	TEMOVATE E (clobetasol propionate) Cream; Topical, 0.05%.	Do.
NDA 020638	VISTIDE (cidofovir) Injectable; Intravenous, 75 mg base/mL.	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404
NDA 021700	AVANDARYL (glimepiride, rosiglitazone maleate) Tablet; Oral, 1 mg/4 mg; 2 mg/4 mg; 4 mg/4 mg; 2 mg/8 mg; 4 mg/8 mg.	SmithKline Beecham (Cork) Ltd., Ireland, 2301 Renaissance Blvd., Mail Code RN 0420, King of Prussia, PA 19406
NDA 022411	OLEPTRO (trazodone HCl); Extended-Release Tablet; Oral, 150 mg; 300 mg.	Angelini Pharma Inc., 8322 Helgerman Ct., Gaithersburg, MD 20877
NDA 050461	ANCEF (cefazolin sodium) Injectable; Intravenous, 1 gram (g)/vial; 10 g/vial.	GlaxoSmithKline, 1 Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101
NDA 050495	AMIKIN (amikacin sulfate) Injectable; Intravenous, EQ 50 mg base/mL; 250 mg base/mL.	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543
ANDA 064169	Cefazolin Sodium Injectable; Intravenous, 500 mg base/vial; 1 g base/vial.	Fresenius Kabi USA, LLC, 3 Corporate Dr., Lake Zurich, IL 60047

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this

document 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 NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. 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 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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