4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1038]

Determination That ROBAXIN and ROBAXIN-750 (Methocarbamol), Oral Tablets, 500 Milligrams and 750 Milligrams, and Other Drug Products, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 011011	ROBAXIN; ROBAXIN-750	Methocarbamol	500 milligrams (mg); 750 mg	Tablet; Oral	Auxilium Pharmaceuticals LLC
NDA 018704	LOPRESSOR	Metoprolol Tartrate	1 mg/milliliter (mL)	Injectable; Injection	Novartis
NDA 018917	SECTRAL	Acebutolol Hydrochloride	Equivalent to (EQ) 200 mg base; EQ 400 mg base	Capsule; Oral	Promius Pharma, LLC
NDA 019546	DYNACIRC	Isradipine	2.5 mg; 5 mg	Capsule; Oral	SmithKline Beecham
NDA 019555	DIPROLENE AF	Betamethasone Dipropionate	EQ 0.05% base	Cream, Augmented; Topical	Merck Sharp Dohme
NDA 019625	ELOCON	Mometasone Furoate	0.10%	Cream; Topical	Merck Sharp Dohme
NDA 020089	ZOVIRAX	Acyclovir	400 mg; 800 mg	Tablet; Oral	Mylan
NDA 020136	DEMADEX	Torsemide	5 mg; 10 mg; 20 mg; 100 mg	Tablet; Oral	Mylan Specialty, L.P.
NDA 020198	ADALAT CC	Nifedipine	30 mg; 60 mg; 90 mg	Tablet, Extended Release; Oral	Alvogen
NDA 020539	LAMISIL	Terbinafine Hydrochloride	EQ 250 mg base	Tablet; Oral	Novartis
NDA 020634	LEVAQUIN	Levofloxacin	250 mg; 500 mg; 750 mg	Tablet; Oral	Janssen Research & Development, LLC
NDA 020716	VICOPROFEN	Hydrocodone Bitartrate; Ibuprofen	7.5 mg; 200 mg	Tablet; Oral	Abbvie, Inc.
NDA 020738	TEVETEN	Eprosartan Mesylate	EQ 300 mg base; EQ 400 mg base; EQ 600 mg base	Tablet; Oral	Abbvie, Inc.
NDA 021001	AXERT	Almotriptan Malate	EQ 6.25 mg base; EQ 12.5 mg base	Tablet; Oral	Janssen Pharms.
NDA 022205	GIAZO	Balsalazide Disodium	1.1 gram	Tablets; Oral	Valeant Pharms. International
NDA 022439	ZUTRIPRO	Chlorpheniramine Maleate, Hydrocodone Bitartrate, and Pseudoephedrine Hydrochloride	4 mg/5 mL; 5 mg/5 mL; 60 mg/5 mL	Solution; Oral	Persion Pharms. LLC
NDA 022510	ABSTRAL	Fentanyl Citrate	EQ 0.1 mg base; EQ 0.2 mg base; EQ 0.3 mg base; EQ 0.4 mg base; EQ 0.6 mg base; EQ 0.8 mg base	Tablet; Sublingual	Sentynl Therapeutics, Inc.

NDA 050011	PATHOCIL	Dicloxacillin Sodium	EQ 250 mg base; EQ 500 mg base	Capsule; Oral	Wyeth-Ayerst Labs
NDA 204308	EPANED KIT	Enalapril Maleate	1 mg/mL	For Solution; Oral	Silvergate Pharms., Inc.
NDA 207233	VIVLODEX	Meloxicam	5 mg; 10 mg	Capsule; Oral	Zyla

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 NDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs. 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 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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