4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2526]

Determination That AQUAMEPHYTON (Phytonadione) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 012223	AQUAMEPHYTON	Phytonadione	10 milligram (mg)/milliliter (mL); 1 mg/0.5 mL	Injectable; Injection	Teligent Pharma Inc.
NDA 016087	VALIUM	Diazepam	5 mg/mL	Injectable; Injection	Roche

NDA 017090	TOFRANIL-PM	Imipramine Pamoate	Equivalent to (EQ) 75 mg HCl; EQ 100 mg HCl; EQ 125 mg HCl; EQ 150 mg HCl	Capsule; Oral	Mallinckrodt Pharmaceuticals
NDA 017558	ROBINUL	Glycopyrrolate	0.2 mg/mL	Injectable; Injection	Eurohealth International Sarl
NDA 017911	CLINORIL	Sulindac	200 mg	Tablet; Oral	Merck
NDA 017962	PARLODEL	Bromocriptine Mesylate	EQ 5 mg base	Capsule; Oral	US Pharmaceuticals Holdings I LLC
NDA 018579	FUROSEMIDE	Furosemide	10 mg/mL	Injectable; Injection	Luitpold Pharmaceuticals, Inc.
NDA 018687	NORMODYNE	Labetalol Hydrochloride	100 mg; 200 mg; 300 mg; 400 mg	Tablet; Oral	Schering-Plough Corp.
NDA 018731	BUSPAR	Buspirone Hydrochloride	5 mg	Tablet; Oral	Bristol-Myers Squibb
NDA 018776	NORCURON	Vecuronium Bromide	10 mg/vial; 20 mg/vial	Injectable; for Injection	Organon USA Inc.
NDA 019773	VENTOLIN	Albuterol Sulfate	EQ 0.083% base	Solution; Inhalation	GlaxoSmithKline
NDA 019810	PRILOSEC	Omeprazole	10 mg; 20 mg; 40 mg	Capsule, Delayed-Release Pellets; Oral	AstraZeneca Pharmaceuticals LP
NDA 020059	ADENOSCAN	Adenosine	60 mg/20 mL (3 mg/mL); 90 mg/30 mL (3 mg/mL)	Solution; I.V. Infusion	Astellas Pharma US, Inc.
NDA 020799	FLOXIN OTIC	Ofloxacin	0.3%	Solution/Drops; Otic	Daiichi-Sankyo
NDA 021045	PLAN B	Levonorgestrel	0.75 mg	Tablet; Oral	Teva Branded Pharm
NDA 021214	RESCULA	Unoprostone Isopropyl	0.15%	Solution/Drops; Ophthalmic	Sucampo Pharmaceuticals, Inc.
NDA 050459	AMOXIL	Amoxicillin	250 mg; 500 mg	Capsule; Oral	GlaxoSmithKline
NDA 050460	AMOXIL	Amoxicillin	125 mg/5mL; 50 mg/mL; 250 mg/5 mL	for Suspension; Oral	GlaxoSmithKline
NDA 050460	LAROTID	Amoxicillin	50 mg/mL	for Suspension; Oral	GlaxoSmithKline
ANDA 072652	ALBUTEROL SULFATE	Albuterol Sulfate	EQ 0.083% base	Solution; Inhalation	Mylan Specialty L.P.

ANDA 075117	ORAPRED	Prednisolone Sodium Phosphate	EQ 15 mg base/5 mL	Solution; Oral	Concordia Pharmaceuticals Inc.
ANDA 075385	BUSPIRONE HYDROCHLORIDE	Buspirone Hydrochloride	5 mg; 10 mg; 15 mg	Tablet; Oral	Teva Pharmaceuticals USA, Inc.
ANDA 078665	LEVONORGESTREL	Levonorgestrel	0.75 mg	Tablet; Oral	Watson Labs
ANDA 087811	PHRENILIN	Acetaminophen; Butalbital	325 mg; 50 mg	Tablet; Oral	Valeant Pharmaceuticals International Inc.
ANDA 088825	BUTALBITAL, ACETAMINOPHEN AND CAFFEINE	Acetaminophen; Butalbital; Caffeine	325 mg; 50 mg; 40 mg	Capsule; Oral	Gilbert Labs

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: August 30, 2016.

Leslie Kux,
Associate Commissioner for Policy.

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