



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2300]

Determination That ARALEN (Chloroquine Phosphate) Oral Tablets, 500 Milligrams, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 006002	ARALEN	Chloroquine Phosphate	500 milligrams (mg)	Tablet; Oral	Sanofi-Aventis U.S. LLC
NDA 006134	DOLOPHINE HYDROCHLORIDE	Methadone Hydrochloride	5 mg; 10 mg	Tablet; Oral	Hikma Pharmaceuticals PLC
NDA 007409	BENTYL	Dicyclomine Hydrochloride	10 mg	Capsule; Oral	Allergan Pharmaceuticals
		Dicyclomine Hydrochloride	20 mg	Tablet; Oral	
NDA 008085	Methotrexate Sodium	Methotrexate Sodium	Equivalent to (EQ) 2.5 mg Base	Tablet; Oral	DAVA Pharmaceuticals, Inc.
NDA 008678	Isoniazid	Isoniazid	100 mg; 300 mg	Tablet; Oral	Sandoz
NDA 012945	DIAMOX	Acetazolamide	500 mg	Extended-Release Capsule; Oral	Teva Branded Pharmaceutical Products
NDA 014103	ONCOVIN	Vincristine Sulfate	1 mg/milliliter (mL); 1 mg/Vial; 5 mg/Vial	Injectable; Injection	Eli Lilly and Co.
NDA 016792	SURMONTIL	Trimipramine Maleate	EQ 25 mg/Base; EQ 50 mg/Base; EQ 100 mg/Base	Capsule; Oral	Teva Women's Health, Inc.
NDA 016801	XYLOCAINE PRESERVATIVE FREE	Lidocaine Hydrochloride	1%; 2%; 4%; 10%; 20%	Injectable; Injection	Fresenius Kabi USA, LLC
NDA 018238	MICRO-K	Potassium Chloride	8 milliequivalents (mEq); 10 mEq	Extended-Release Capsule; Oral	Nesher Pharmaceuticals LLC
NDA 019568	DERMATOP	Prednicarbate	0.10%	Ointment; Topical	Valeant Pharmaceuticals
NDA 020192	LAMISIL	Terbinafine Hydrochloride	1%	Cream; Topical	Novartis
NDA 020482	PRECOSE	Acarbose	25 mg; 50 mg; 100 mg	Tablet; Oral	Bayer Healthcare
NDA 020591	TARKA	Trandolapril; Verapamil Hydrochloride	1 mg; 240 mg	Extended-Release Tablet; Oral	AbbVie Inc.
NDA 020635	LEVAQUIN	Levofloxacin	EQ 500 mg/20 mL; EQ 750 mg/30 mL	Injectable; Injection	Janssen Pharmaceuticals, Inc.
NDA 020823	EXELON	Rivastigmine Tartrate	EQ 1.5 mg Base; EQ 3 mg Base; EQ 4.5 mg Base; EQ 6 mg Base	Capsule; Oral	Novartis
NDA 020920	NATRECOR	Nesiritide	1.5 mg/Vial	For Solution; Intravenous	Scios Inc.
NDA 021549	EMEND	Aprepitant	40 mg	Capsule; Oral	Merck
NDA 021590	FAZACLO ODT	Clozapine	12.5 mg; 25 mg; 100 mg; 150 mg; and 200 mg	Orally Disintegrating Tablet; Oral	Jazz Pharmaceuticals PLC

NDA 202535	PREPOPIK	Citric Acid, Magnesium Oxide, and Sodium Picosulfate	12 grams (g)/Packet; 3.5 g/Packet; 10 mg/Packet	For Solution; Oral	Ferring Pharmaceuticals Inc.
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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 and ANDAs listed 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: January 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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