



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-4734]

Determination that DEMEROL (Meperidine Hydrochloride) Tablet, 100 Milligrams, and Other Drug Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 table 1 are no longer being marketed.

Table 1.--Drug Products Not Withdrawn From Sale for Reasons of Safety or Effectiveness

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 005010	DEMEROL	Meperidine Hydrochloride	100 Milligrams (mg)	Tablet; Oral	Quagen Pharmaceuticals LLC
NDA 009402	DELESTROGEN	Estradiol Valerate	40 mg/Milliliter (mL)	Injectable; Injection	Endo Operations Ltd.
NDA 011338	FLUOTHANE	Halothane	99.99%	Liquid; Inhalation	Wyeth-Ayerst Laboratories
NDA 017354	LOESTRIN FE 1/20	Ethinyl Estradiol, Norethindrone Acetate	0.02 mg, 1 mg	Tablet; Oral	Teva Branded Pharmaceutical Products R&D Inc.
NDA 018063	CORGARD	Nadolol	20 mg; 40 mg; 80 mg	Tablet; Oral	US WorldMeds, LLC
NDA 019429	FIORINAL W/CODEINE	Aspirin, Butalbital, Caffeine, Codeine Phosphate	325 mg, 50mg, 40 mg, 30mg	Capsule; Oral	Allergan
NDA 019758	CLOZARIL	Clozapine	50 mg; 200 mg	Tablet; Oral	Heritage Life Sciences Barbados Inc.
NDA 020496	AMARYL	Glimepiride	1 mg; 2 mg; 4 mg	Tablet; Oral	Sanofi-Aventis U.S. LLC
NDA 020768	ZOMIG	Zolmitriptan	2.5 mg; 5 mg	Tablet; Oral	IPR Pharmaceuticals, Inc.
NDA 020933	VIRAMUNE	Nevirapine	50 mg/5 mL	Suspension; Oral	Boehringer Ingelheim Pharmaceuticals Inc.
NDA 021123	ULTRACET	Acetaminophen, Tramadol Hydrochloride	325 mg, 37.5 mg	Tablet; Oral	Janssen Pharmaceuticals Inc.
NDA 021142	OLUX	Clobetasol Propionate	0.05%	Aerosol, Foam; Topical	Norvium Bioscience, LLC
NDA 021231	ZOMIG-ZMT	Zolmitriptan	2.5 mg; 5 mg	Orally Disintegrating Tablet; Oral	AstraZeneca Pharmaceuticals LP
NDA 021368	CIALIS	Tadalafil	2.5 mg	Tablet; Oral	Eli Lilly and Co.
NDA 021497	ALINIA	Nitazoxanide	500 mg	Tablet; Oral	Romark Laboratories
NDA 021636	ZEGERID	Omeprazole, Sodium Bicarbonate	20 mg/Package, 1.68 grams (g)/Package; 40 mg/Package, 1.68 g/Package	For Suspension; Oral	Salix Pharmaceuticals Inc.
NDA 021689	NEXIUM IV	Esomeprazole Sodium	EQ 40 mg Base/Vial	Injectable; Intravenous	AstraZeneca Pharmaceuticals LP
NDA 021799	QUALAQUIN	Quinine Sulfate	324 mg	Capsule; Oral	Sun Pharmaceutical Industries, Inc.
NDA 021937	ATRIPLA	Efavirenz, Emtricitabine, Tenofovir Disoproxil Fumarate	600 mg, 200 mg, 300 mg	Tablet; Oral	Gilead Sciences, Inc.
NDA 021963	ALLEGRA	Fexofenadine Hydrochloride	30 mg/5 mL	Suspension; Oral	Chattem Inc., DBA Sanofi Consumer Healthcare

NDA 022331	KAPVAY	Clonidine Hydrochloride	0.1 mg	Extended-Release Tablet; Oral	Concordia Pharmaceuticals, Inc.
NDA 022352	COLCRYS	Colchicine	0.6 mg	Tablet; Oral	Takeda Pharmaceuticals USA, Inc.
NDA 050682	COSMEGEN	Dactinomycin	0.5 mg/Vial	Injectable; Injection	Recordati Rare Diseases Inc.
NDA 050717	MONUROL	Fosfomycin Tromethamine	EQ 3 g Base/Packet	For Solution; Oral	Zambon Company S.p.A.
ANDA 086162	BUTALBITAL, ASPIRIN AND CAFFEINE	Aspirin, Butalbital, Caffeine	325 mg, 50 mg, 40 mg	Tablet; Oral	Hikma International Pharmaceuticals LLC
ANDA 087056	CYPROHEPTADINE HYDROCHLORIDE	Cyproheptadine Hydrochloride	4 mg	Tablet; Oral	Avet Pharmaceuticals
ANDA 088763	PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE	Codeine Phosphate, Promethazine Hydrochloride	10mg/5mL, 6.25mg/5mL	Syrup; Oral	Actavis Mid-Atlantic, LLC

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.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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