4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1569]

Determination That NALFON (Fenoprofen Calcium) Oral Capsules, Equivalent to 300 Milligram Base, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 017604	NALFON	Fenoprofen Calcium	Equivalent to (EQ) 300 Milligrams (mg) Base	Capsule; Oral	Xspire Pharma
NDA 017087	ETHRANE	Enflurane	99.9%	Liquid; Inhalation	Baxter Healthcare Corp.
NDA 018801	STERILE WATER FOR INJECTION	Sterile Water For Injection	100% (1 Milliliter (mL)); 100% (5.2 mL)	Liquid; N/A	Hospira, A Pfizer Company
NDA 019152	CALAN SR	Verapamil Hydrochloride	120 mg; 180 mg, 240 mg	Tablet, Extended Release; Oral	Pfizer Inc.
NDA 019885	ACCUPRIL	Quinapril Hydrochloride	EQ 5 mg Base; EQ 10 mg Base; EQ 20 mg Base; EQ 40 mg Base	Tablet; Oral	Pfizer Pharmaceuticals Ltd.
NDA 019941	EMLA	Lidocaine; Prilocaine	2.5%; 2.5%	Cream; Topical	Teva Branded Pharmaceutical Products R & D Inc
NDA 020105	TRIOSTAT	Liothyronine Sodium	EQ 0.01 mg Base/mL	Injectable; Injection	Par Sterile Products, LLC
NDA 020125	ACCURETIC	Hydrochlorothiazide; Quinapril Hydrochloride	12.5 mg, EQ 10 mg Base; 12.5 mg, EQ 20 mg Base; 25 mg, EQ 20 mg Base	Tablet; Oral	Pfizer Pharmaceuticals Ltd.
NDA 020406	PREVACID	Lansoprazole	15 mg	Capsule, Delayed Release Pellets; Oral	Takeda Pharmaceuticals USA, Inc
NDA 020666	ALBENZA	Albendazole	200 mg	Tablet; Oral	Impax Laboratories Inc.
NDA 020723	ALDARA	Imiquimod	5%	Cream; Topical	Bausch Health US LLC
NDA 020972	SUSTIVA	Efavirenz	50 mg; 200 mg	Capsule; Oral	Bristol Myers Squibb Co.
NDA 021009	ALOCRIL	Nedocromil Sodium	2%	Solution/Drops; Ophthalmic	Allergan Inc.
NDA 021526	RANEXA	Ranolazine	500 mg; 1 g	Tablet, Extended Release; Oral	Menarini International Operations Luxembourg SA
NDA 021565	ELESTAT	Epinastine Hydrochloride	0.05%	Solution/Drops; Ophthalmic	Allergan Inc.
NDA 021775	ENTEREG	Alvimopan	12 mg	Capsule; Oral	Cubist Pharmaceuticals, Inc
NDA 021790	DACOGEN	Decitabine	50 mg/Vial	Injectable; Intravenous	Otsuka Pharmaceutical Co., Ltd.
NDA 050095	CAPASTAT SULFATE	Capreomycin Sulfate	EQ 1 g Base/Vial	Injectable; Injection	Epic Pharma, LLC

NDA 050795	DORYX	Doxycycline Hyclate	EQ 50 mg Base; EQ 100 mg Base; EQ 120 mg Base	Tablet, Delayed Release; Oral	Mayne Pharma International Pty Ltd.
NDA 050801	EVOCLIN	Clindamycin Phosphate	1%	Aerosol, Foam; Topical	Mylan Pharmaceuticals Inc.
NDA 200179	STAXYN	Vardenafil Hydrochloride	10 mg	Tablet, Orally Disintegrating; Oral	Bayer Healthcare Pharmaceuticals Inc.
NDA 202515	MORPHINE SULFATE	Morphine Sulfate	15 mg/mL	Injectable; Injection	Hospira, A Pfizer Company
NDA 203667	MINASTRIN 24 FE	Ethinyl Estradiol; Norethindrone Acetate	0.02mg, 1mg	Tablet; Oral	Allergan Pharmaceuticals International, Ltd.
NDA 210854	XOFLUZA	Baloxavir Marboxil	20 mg	Tablet; Oral	Genentech, Inc.

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.

Dated: April 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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