4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1703]

Determination That CATAPRES (Clonidine Hydrochloride) Tablets, 0.1 Milligrams; 0.2 Milligrams; and 0.3 Milligrams, and Other Drug Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 017407	CATAPRES	Clonidine Hydrochloride	0.1 Milligrams (mg); 0.2 mg; 0.3 mg	Tablet; Oral	Boehringer Ingelheim
NDA 017534	FIORINAL	Aspirin; Butalbital; Caffeine	325 mg; 50 mg; 40 mg	Capsule; Oral	Allergan Sales
NDA 017876	LOESTRIN 21 1/20	Ethinyl Estradiol; Norethindrone Acetate	0.02 mg; 1 mg	Tablet; Oral	Teva Branded Pharms.
NDA 018647	CORZIDE	Bendroflumethiazide; Nadolol	5 mg; 40 mg; 5 mg; 80 mg	Tablet; Oral	King Pharms., LLC
NDA 018685	GAVISCON	Aluminum Hydroxide; Magnesium Trisilicate	80 mg; 20 mg; 160 mg, 40 mg	Tablet; Oral	Chattem
NDA 018751	SPECTAZOLE	Econazole Nitrate	1%	Cream; Topical	Alvogen, Inc.
NDA 019813	DURAGESIC-100	Fentanyl	100 Micrograms (mcg)/Hour; 12.5 mcg/Hour; 25 mcg/Hour; 37.5 mcg/Hour; 50 mcg/Hour; 75 mcg/Hour	Film, Extended Release; Transdermal	Janssen Pharms.
NDA 020519	CICLOPIROX	Ciclopirox	0.77%	Gel; Topical	Alvogen, Inc.
NDA 021015	ANDROGEL	Testosterone	25 mg/2.5 Grams (g) Packet; 50 mg/5 g Packet	Gel; Transdermal	Besins Healthcare
NDA 021152	CUTIVATE	Fluticasone Propionate	0.05%	Lotion; Topical	Fougera Pharms.
NDA 021169	RAZADYNE	Galantamine Hydrobromide	Equivalent to (EQ) 4 mg Base; EQ 8 mg Base; EQ 12 mg Base	Tablet; Oral	Janssen Pharms.
NDA 021567	REYATAZ	Atazanavir Sulfate	EQ 150 mg Base	Capsule; Oral	Bristol Myers Squibb
NDA 021695	ANTARA (MICRONIZED)	Fenofibrate	30 mg	Capsule; Oral	Lupin
NDA 022107	TEKTURNA HCT	Aliskiren Hemifumarate; Hydrochlorothiazide	EQ 150 mg Base; 12.5 mg; EQ 150 mg Base; 25 mg; 300 mg; 12.5 mg; 300 mg; 25 mg	Tablet; Oral	Noden Pharma.

NDA 022309	ANDROGEL	Testosterone	1.62% (20.25 mg/1.25 g Packet); 1.62% (40.5 mg/2.5 g Packet)	Gel; Transdermal	Besins Healthcare
NDA 022401	TWYNSTA	Amlodipine Besylate; Telmisartan	EQ 5 mg Base; 40 mg; EQ 10 mg Base; 40 mg; EQ 5 mg Base; 80 mg; EQ 10 mg Base; 80 mg	Tablet; Oral	Boehringer Ingelheim
NDA 022426	OSENI	Alogliptin Benzoate; Pioglitazone Hydrochloride	EQ 12.5 mg Base; EQ 15 mg Base; EQ 12.5 mg Base; EQ 45 mg Base	Tablet; Oral	Takeda Pharms. USA
NDA 050824	OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN	Amoxicillin; Clarithromycin; Omeprazole	500 mg, n/a, n/a; n/a, 500 mg, n/a; n/a, n/a, 20 mg	Capsule, Tablet, Capsule, Delayed Release; Oral	Cumberland Pharms.

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: May 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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