marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Tack Endovascular System (6F) is 1,338 days. Of this time, 1,114 days occurred during the testing phase of the regulatory review period, while 224 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* August 14, 2015. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective August 14, 2015.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 31, 2018. FDA has verified the applicant's claim that the premarket approval application (PMA) for Tack Endovascular System (6F) (PMA P180034) was initially submitted August 31, 2018.

3. *The date the application was approved:* April 11, 2019. FDA has verified the applicant's claim that PMA P180034 was approved on April 11, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 485 days or 621 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10297 Filed 5–12–23; 8:45 am]

BILLING CODE 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.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
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.

[FR Doc. 2023–10296 Filed 5–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in