Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 9, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 9, 2023 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26661 Filed 12–7–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0585]

Determination That NORFLEX (Orphenadrine Citrate) Injection, 30 Milligrams/Milliliter, and NORFLEX (Orphenadrine Citrate) Extended-Release Tablet, 100 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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, Agency, or we) has determined that NORFLEX (orphenadrine citrate) Injection, 30 milligrams (mg)/milliliter (mL), and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, were not withdrawn from sale for reasons of safety or effectiveness.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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Anuj Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–2246, *Anuj.Shah@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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, is the subject of NDA 013055, held by Pai Holdings LLC DBA Pharmaceutical Associates Inc., and initially approved on October 2, 1960. NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, is the subject of NDA 012157, held by Bausch Health US LLC, and initially approved on November 2, 1959. Both NORFLEX drug products are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions.

Both NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Odin Pharmaceuticals, LLC, submitted a citizen petition dated April 11, 2022 (Docket No. FDA–2022–P–0585), under 21 CFR 10.30, requesting that the Agency determine whether NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 100 mg extended-release tablet, that dosage form and strength has also been discontinued. On our own initiative, we have also determined whether that dosage form and strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet

current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26663 Filed 12–7–22; 8:45 am]

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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 the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on October 1, 2022, through October 31, 2022. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Health Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court's caption (Petitioner's Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Carole Johnson,

Administrator.

List of Petitions Filed

1. Thomas Mayo, Wauwatosa, Wisconsin, Court of Federal Claims No: 22–1421V
2. Marsha Pavlik Wood, Stow, Ohio, Court of Federal Claims No: 22–1422V
3. Ella Burroughs, Phoenix, Arizona, Court of Federal Claims No: 22–1423V
4. Sylvia Kline on behalf of B.H., Phoenix, Arizona, Court of Federal Claims No: 22–1424V
5. Ross Kleiman, Boston, Massachusetts, Court of Federal Claims No: 22–1426V
6. Lindsey Alvarez, Fullerton, California, Court of Federal Claims No: 22–1428V
7. Deanna A. Finch, Newport, Tennessee, Court of Federal Claims No: 22–1429V
8. Larry Pierce, Kansas City, Kansas, Court of Federal Claims No: 22–1432V
9. Joann Bauer, Duluth, Minnesota, Court of Federal Claims No: 22–1440V
10. Arthur Passarelli, Washington, District of Columbia, Court of Federal Claims No: 22–1443V
11. James Thurston and Valerie Thurston on behalf of A.T., Lakeland, Florida, Court of Federal Claims No: 22–1444V
12. Andrea Cuatt, Los Angeles, California, Court of Federal Claims No: 22–1447V
13. Judith Wertin, Fort Bragg, California, Court of Federal Claims No: 22–1449V
14. Grace Laurin, Plattsburgh, New York, Court of Federal Claims No: 22–1450V
15. Stacey R. Williams, Fort Bragg, North Carolina, Court of Federal Claims No: 22–1451V
16. Juliet Hawk, San Diego, California, Court of Federal Claims No: 22–1454V
17. Kenneth Ingalsbe, Batavia, New York, Court of Federal Claims No: 22–1457V
18. Meaghan Clifford, Boston, Massachusetts, Court of Federal Claims No: 22–1458V
19. Karessa Hinson-Sherwood, Gainesville, Florida, Court of Federal Claims No: 22–1461V
20. Tiffany Wentworth, Simsbury,