DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0671]

Determination That PARAFLEX (Chlorzoxazone) Tablets, 250 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA) has determined that PARAFLEX (Chlorzoxazone) Tablets, 250 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for PARAFLEX (Chlorzoxazone) Tablets, 250 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kathy Schreier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6252, Silver Spring, MD 20993–0002, 301–796–3432.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

PARAFLEX (Chlorzoxazone) Tablets, 250 mg, is the subject of NDA 11–300, held by Ortho McNeil Pharm, and was initially approved on December 12, 1958. PARAFLEX is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

In letters dated April 11, 1997, and April 22, 1997, a former NDA holder, The R.W. Johnson Pharmaceutical Research Institute, notified FDA that PARAFLEX (Chlorzoxazone) Tablets, 250 mg, had been discontinued and requested withdrawal of NDA 11–300, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of September 25, 1997 (62 FR 50387), FDA announced that it was withdrawing approval of NDA 11–300, effective September 25, 1997.

Lachman Consultant Services, Inc., submitted a citizen petition dated June 4, 2013 (Docket No. FDA–2013–P–0671), under 21 CFR 10.30, requesting that the Agency determine whether PARAFLEX (Chlorzoxazone) Tablets, 250 mg, was withdrawn from sale for reasons of safety or effectiveness.

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 PARAFLEX (Chlorzoxazone) Tablets, 250 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PARAFLEX (Chlorzoxazone) Tablets, 250 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PARAFLEX (Chlorzoxazone) Tablets, 250 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 this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PARAFLEX (Chlorzoxazone) Tablets, 250 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. ANDAs that refer to PARAFLEX (Chlorzoxazone) Tablets, 250 mg, may 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: October 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24781 Filed 10–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0503]

Determination That Potassium Citrate, 10 Milliequivalents/Packet and 20 Milliequivalents/Packet, Was 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) has determined that Potassium Citrate, 10 milliequivalents/packet (mEq/packet) and 20 mEq/packet, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Potassium Citrate, 10 mEq/packet and 20 mEq/packet, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6224, Silver Spring, MD 20993–0002, 301–796–3977.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate

versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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 approving 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.

Potassium Citrate, 10 mEq/packet and 20 mEq/packet, is the subject of NDA 19–647, held by Nova-K LLC, and initially approved on October 13, 1988. Potassium Citrate is indicated for the management of renal tubular acidosis with calcium stones, hypocitraturic calcium oxalate nephrolithiasis of any etiology, and uric acid lithiasis with or without calcium stones.

Potassium Citrate, 10 mEq/packet and 20 mEq/packet, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Nomax, Inc., submitted a citizen petition dated April 18, 2013 (Docket No. FDA–2013–P–0503), under 21 CFR 10.30, requesting that the Agency determine whether Potassium Citrate, 10 mEq/packet and 20 mEq/packet, was withdrawn from sale for reasons of safety or effectiveness.

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 Potassium Citrate, 10 mEq/packet and 20 mEq/packet, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Potassium Citrate, 10 mEq/packet and 20 mEq/packet, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Potassium Citrate, 10 mEq/packet and 20 mEq/packet, 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 this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Potassium Citrate, 10 mEq/packet and 20 mEq/packet, 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. ANDAs that refer to Potassium Citrate, 10 mEq/packet and 20 mEq/packet, may 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: October 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24780 Filed 10–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Peptide Inhibitor of p38 Mapk Signaling for the Treatment of Inflammatory Autoimmune Diseases and Inflammatory Cancers

Description of Technology: This invention relates to a peptide fragment of GADD45A growth arrest and DNA-damage-inducible, alpha (Gadd45a), a protein involved in the p38 Map kinase signaling pathway. Although the fragment is only 15 amino acids in length, it retains the functionality of Gadd45a by inhibiting enzymatic activity of tyrosine-323-phosphorylaled p38 *in vitro.* The peptide fragment is tagged to render it cell-permeable and, according to *in vitro* studies, it exhibits minimal toxicity. The inventors have found that the fragment readily penetrates T cells to inhibit (a) proliferation in response to T cell receptor-mediated stimulation; (b) skewing of T cells to Th I and Th 17 cells; and (c) inflammatory cytokine production. As a result, this fragment has anti-inflammatory properties and has potential as a therapeutic for inflammatory autoimmune conditions or inflammatory cancers, such as pancreatic cancer.

Potential Commercial Applications: Treatment for inflammatory autoimmune conditions or inflammatory cancers, such as pancreatic cancer.

Competitive Advantages: Minimal cellular toxicity.

Development Stage: In vitro data available.

Inventors: Jonathan D. Ashwell, Mohammed S. Alam, Paul R. Mittelstadt (all of NCI).

Intellectual Property:

- HHS Reference No. E–281–2012/0—US Provisional Application No. 61/728,368 filed 20 Nov 2012.
- HHS Reference No. E–281–2012/1—US Provisional Application No. 61/774,066 filed 07 Mar 2013.

Licensing Contact: Jaime M. Greene; 301–435–5559; *greenejaime@mail.nih.gov*.