DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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August 8, 2007

Kalpana Rao
GVP, Regulatory Affairs (Global)
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, NY 10532

Re: Docket No. 2006P-0446/CP1

Dear Ms. Rao:

This responds to your citizen petition received on November 1, 2006, requesting that the Food and Drug Administration (FDA) determine whether PHENERGAN (promethazine hydrochloride) Suppositories, 12.5 milligrams (mg) and 25 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that PHENERGAN (promethazine hydrochloride) Suppositories, 12.5 mg and 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain PHENERGAN (promethazine hydrochloride) Suppositories, 12.5 mg and 25 mg, in the "Discontinued Drug Product List" section of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announced the FDA determination. If you require any further information, please feel free to call me at 301-594-2041.

Sincerely yours,

Mary Catchings

Mary Catchings
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2006P-0446

LET 2

ANDA that does not refer to a listed drug.

PHOSLO (calcium acetate) 667-mg tablet, equal to 169 mg calcium, is the subject of approved NDA 19–976 held by Fresenius Medical Care (Fresenius). PHOSLO (calcium acetate) 667-mg tablet is indicated for the control of hyperphosphatemia in end stage renal failure. Fresenius's NDA 19–976 was approved on December 10, 1990. Lachman Consultant Services, Inc., and Beckloff Associates, submitted citizen petitions dated July 14, 2006 (Docket No. 2006P–0287/CP1) and September 27, 2006 (Docket No. 2006P–0399), respectively, under 21 CFR 10.30, requesting that the agency determine, as described in § 314.161, whether PHOSLO (calcium acetate) 667-mg tablet was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Fresenius's PHOSLO (calcium acetate) 667-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. FDA has reviewed its files for records concerning the withdrawal of PHOSLO (calcium acetate) 667-mg tablet from sale. There is no indication that the decision to discontinue marketing of PHOSLO (calcium acetate) 667-mg tablet was a function of safety or effectiveness concerns, and the petitioner has identified no data or information suggesting that PHOSLO (calcium acetate) 667-mg tablet was withdrawn for safety or effectiveness reasons. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that PHOSLO (calcium acetate) 667-mg tablet was withdrawn for reasons of safety or effectiveness.[1]

After considering the citizen petitions and reviewing agency records, FDA determines that for the reasons outlined in this document, PHOSLO (calcium acetate) 667-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHOSLO (calcium acetate) 667-mg tablet 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 PHOSLO (calcium acetate) 667-mg tablet may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. 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.

[1]Beckloff Associates also requested that the agency determine whether PHOSLO (calcium acetate) 667-mg capsule was withdrawn from sale for reasons of safety or effectiveness. Because a capsule dosage form for this product is currently marketed, such a determination is not necessary (See NDA 21–160, product no. 3).

Dated: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15172 Filed 8–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0446]

Determination That PHENERGAN (Promethazine Hydrochloride) Suppositories, 12.5 Milligrams and 25 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) has determined that PHENERGAN (promethazine hydrochloride (HCl)) suppositories, 12.5 milligrams (mg) and 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for promethazine HCl suppositories, 12.5 mg and 25 mg.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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 generally known 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 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)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, are the subject of approved NDA 10–926 held by Wyeth Pharmaceuticals, Inc. (Wyeth). PHENERGAN (promethazine HCl) suppositories are indicated for, among other things, certain types of allergic reactions and sedation. Wyeth's NDA 10–926 was originally approved in 1958. In 1971, under the Drug Efficacy Study Implementation (DESI), FDA concluded that promethazine HCl rectal suppositories were effective or probably effective for the indications described in the **Federal Register** notice published on June 18, 1971 (DESI 6290, 36 FR 11758). In a citizen petition received November 1, 2006 (Docket No. 2006P–0446/CP1), submitted under 21 CFR 10.30, Taro Pharmaceuticals U.S.A., Inc., requested that the agency determine, as described in § 314.161, whether PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that promethazine HCl is a widely used product that has been marketed for many decades in many dosage forms. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that PHENERGAN

suppositories, 12.5 mg and 25 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined in this notice, PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 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 PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. 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: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15174 Filed 8–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0160]

Determination That Daranide (Dichlorphenamide) Tablets, 50 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) has determined that Daranide (dichlorphenamide) Tablets, 50 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dichlorphenamide tablets, 50 mg.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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 generally known 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).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated April 12, 2006 (Docket No. 2006P–0160/CP1), submitted under 21 CFR 10.30, Taro Research Institute requested that the agency determine whether Daranide Tablets, 50 mg, were withdrawn from sale for reasons of safety or effectiveness. Daranide (dichlorphenamide) Tablets, 50 mg, are the subject of approved NDA 11–366 held by Merck & Co., Inc. (Merck). Daranide is indicated for adjunctive treatment of glaucoma. Merck discontinued marketing Daranide Tablets, 50 mg, in June 2002, and they were moved to the "Discontinued Drug Product List" section of the Orange Book.

The agency has determined that Daranide Tablets, 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that Daranide Tablets, 50 mg, were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined in this notice, Daranide (dichlorphenamide) Tablets, 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Daranide (dichlorphenamide) Tablets, 50 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 Daranide (dichlorphenamide) Tablets, 50 mg, may be approved by the agency as long as they comply with relevant legal and regulatory requirements. 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: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15230 Filed 8–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected