DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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August 8, 2007

Miguel A. de Soto-Perera, Ph.D
Beckloff Associates
7400 West 110th Street, Suite 300
Overland Park, Kansas 66210

Re: Docket No. 2006P-0399/CP1

Dear Mr. de Soto-Perera:

This letter responds to your citizen petition dated September 27, 2006, requesting that the FDA determine whether Phoslo (calcium acetate) 667-milligram (mg) tablet, equal to 169 mg calcium, has been withdrawn from sale for safety or efficacy reasons. 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).

The FDA has reviewed its records and determined that Phoslo (calcium acetate) 667-mg tablet, equal to 169 mg calcium, was not withdrawn from sale for reasons of safety or effectiveness. The FDA will maintain Phoslo (calcium acetate) 667-mg tablet, equal to 169 mg calcium, in the "Discontinued Drug Product List" of *Approved Drugs with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, do not hesitate to contact me at (301) 594-2041.

Sincerely,

Nikki Mueller
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2006P-0399

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instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

State of Pennsylvania Fire and Life Safety Public Education Survey—New—Division of Unintentional Injury, National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project will involve conducting a statewide survey of Pennsylvania fire departments to identify current fire and life safety education programs, resources, and training needs. Survey findings will be used to develop an inventory of programs and resources, and to inform future training programs for fire and life safety educators in Pennsylvania. In the United States each year, there are approximately 400,000 residential fires, with 14,000 non-fatal and 3,000 fatal civilian injuries. In line with Healthy People 2010 objectives, National Center of Injury Prevention and Control (NCIPC) works to reduce and eliminate non-fatal and fatal injuries from residential fires.

The survey will be conducted with fire departments in Pennsylvania. The 2007 National Directory of Fire Chiefs & EMS Administrators lists all fire departments in Pennsylvania along with their contact information. Fire departments will be asked to complete a 35-item survey either on-line or by returning a paper survey. It is expected that 1,000 fire departments will complete the 30 minute survey, which is designed to collect information on the scope and content of educational programs and activities, training needs, and barriers to fire and life safety education. An initial mailing (and e-mail if e-mail address exists) to the fire chief of each fire department will include a postcard describing the study and instructing them how to submit the survey. Fire departments that have not completed the survey and have not declined will be sent a reminder postcard and will receive a follow-up telephone call.

There are no costs to respondents except for their time to participate in the surveys.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Fire Departments—Completed survey	1,000	1	30/60	500
Total				500

Dated: July 31, 2007.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–15218 Filed 8–3–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006P–0287 and 2006P–0399]

Determination That PHOSLO (Calcium Acetate) 667-Milligram Tablet 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 PHOSLO (calcium acetate) 667-milligram (mg) tablet, equal to 169 mg calcium, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for calcium acetate 667-mg tablet.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, 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 withdrawn 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)(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.

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.

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

[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).

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