RES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 8-3-07
Publication Date 8-6-07
Certifier A. Corbin

Food and Drug Administration

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

QS per Lyle Jaffe 8-1-07

Determination That PHOSLO (Calcium Acetate) 667-Milligram Tablet Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that PHOSLO (calcium acetate) 667-milligram (mg) tablet, equal to 169 mg calcium, was not withdrawn from sale for reasons of safety or effectiveness.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).

2006P-0287

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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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

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[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. 07–????? Filed ??–??–07; 8:45 am]

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