## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–P–0257]**

### Determination That Theophylline Oral Solution, 80 Milligrams/15 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA) has determined that theophylline oral solution, 80 milligrams (mg)/15 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for theophylline oral solution, 80 mg/15 mL, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Nancy Hayes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6244, Silver Spring, MD 20993–0002, 301–796–3601.

**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 approved 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 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

Theophylline oral solution, 80 mg/15 mL, is the subject of ANDA 087449, held by Roxane Laboratories, Inc. (Roxane), and initially approved on September 15, 1983. ANDA 087449 was identified in the Orange Book as the listed drug for theophylline oral solution, 80 mg/15 mL.

According to the latest version of the approved labeling for theophylline oral solution, 80 mg/15 mL, theophylline is indicated for the treatment of the symptoms and reversible airflow obstruction associated with chronic asthma and other chronic lung diseases, such as emphysema and chronic bronchitis. Roxane notified FDA by letter dated August 4, 2008, that it was no longer marketing theophylline oral solution, 80 mg/15 mL and requested that ANDA 087449 be withdrawn. Theophylline oral solution, 80 mg/15 mL was moved to the "Discontinued Drug Product List" section of the Orange Book.

Silarx Pharmaceuticals, Inc. (Silarx or petitioner), submitted a citizen petition to FDA dated May 29, 2009 (Docket No. FDA–2009–P–0257), under 21 CFR 10.30, requesting that the Agency accept an ANDA submitted by Silarx for theophylline oral solution 80 mg/15 mL, referencing ANDA 087449 as the listed drug. FDA cannot approve the petitioner's ANDA or any ANDA unless it first determines whether ANDA 087449 was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined, under § 314.161, that theophylline oral solution, 80 mg/15 mL, ANDA 087449, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that theophylline oral solution, 80 mg/15 mL, was withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of theophylline oral solution, 80 mg/15 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and 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 theophylline oral solution, 80 mg/15 mL, 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 theophylline oral solution, 80 mg/15 mL, may be approved by the Agency if 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: February 15, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Office of Urban Indian Health Programs; Announcement Type: Limited Competition, Continuation; Funding Announcement Number: HHS–2011–IHS–UIHP–0001

Catalogue of Federal Domestic Assistance Number: 93.193

*Key Dates: Application Deadline Date:* March 23, 2011.

*Review Period:* April 25–27, 2011.

*Earliest Anticipated Start Date:* May 16, 2011.

#### I. Funding Opportunity Description

*Statutory Authority*

The Indian Health Service (IHS), Office of Urban Indian Health Programs (OUIHP), announces the FY 2011 limited competition, continuation grants for continued operation support for the 4-in-1 Title V grants to make health care services more accessible for American Indians and Alaska Natives (AI/AN) residing in urban areas. This program is authorized under the authority of the Snyder Act, 25 U.S.C. 1652, 1653, 1660a of Title V of the Indian Health Care Improvement Act (IHCIA), Public Law 94–437, as amended.