DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–P–0474] (formerly Docket No. 2004P–0262)

Withdrawal of Approval of 128 Suitability Petitions; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 23, 2007 (72 FR 8184). The notice announced that FDA was withdrawing approval of 128 suitability petitions in accordance with the Pediatric Research Equity Act of 2003 (PREA). FDA has determined that approval of the suitability petition submitted by Roxane Laboratories, Inc. (Roxane), for lorazepam oral solution, 1 milligram (mg)/10 milliliters (mL) (Docket No. FDA–1994–P–0017),[1] should not have been withdrawn and therefore retroactively reinstates its approval of that petition. This document also corrects errors in the petition numbers for two of the suitability petitions listed in the notice.

FOR FURTHER INFORMATION CONTACT: Cecelia M. Parise,Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 23, 2007 (72 FR 8184), FDA announced that it was withdrawing approval of 128 suitability petitions in accordance with PREA. Prior to PREA's enactment, FDA had approved these suitability petitions to permit abbreviated new drug applications (ANDAs) to be submitted for drugs that had a different active ingredient, dosage form, or route of administration than their reference listed drugs. In the notice, FDA explained that the approval of these suitability petitions was being withdrawn because ANDAs were never submitted and PREA requires that all applications submitted on or after April 1, 1999, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration contain an assessment of the safety and effectiveness of the drug for the claimed indications in relevant pediatric subpopulations unless the requirement is waived or deferred. Thus, these suitability petitions no longer satisfied the conditions for approval. The notice became effective on March 26, 2007.

In response to the notice, Roxane sent FDA a letter dated March 1, 2007, regarding the withdrawal of approval of its suitability petition for lorazepam oral solution, 1 mg/10 mL (Docket No. FDA–1994–P–0017). Roxane stated that it submitted ANDA 74–648 for lorazepam oral solution, 1 mg/10 mL, on the basis of the approval of its suitability petition for lorazepam oral solution, 1 mg/10 mL (Docket No. FDA–1994–P–0017). Roxane also stated that during the review of the ANDA, they were asked to change the name of the product to lorazepam oral solution, 0.5 mg/5 mL, and the ANDA was approved on March 18, 1997. FDA has reviewed its records and determined that ANDA 74–648 was submitted under suitability petition no. 94P–0199/CP1 before April 1, 1999; therefore, approval of this suitability petition should not have been withdrawn. This document corrects the error and retroactively reinstates approval of the suitability petition for lorazepam oral solution, 1 mg/10 mL (Docket No. FDA–1994–P–0017).

In addition, FDA has determined that the notice contained incorrect petition numbers for two of the suitability petitions. This document corrects those errors.

In FR Doc. E7–3043, appearing on page 8184 in the **Federal Register** of Friday, February 23, 2007, the following corrections are made:

1. On page 8185, in the table, in the first column, for Petition No., ''85P–0095/CP1'' is corrected to read ''83N–0095/CP1''.

2. On page 8187, in the table, in the first column, for Petition No., ''92P–0332/CP1'' is corrected to read ''92P–0232/CP1''.

3. On page 8187, in the table, in the first column, for Petition No., ''94P–0199/CP1'' is deleted.

Dated: September 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23721 Filed 10–6–08; 8:45 am]

BILLING CODE 4160–01–S

[1] This citizen petition was originally assigned docket number 94P-0199. The number was changed to FDA–1994–P–0017 as a result of FDA's transition to its new docketing system (*http://www.Regulations.gov*) in January 2008.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children, OPM-306

Correction

In notice document E8–22359 beginning on page 55122 in the issue ofWednesday, September 24, 2008, make the following corrections:

1. On page 55122, in the third column, in the second full paragraph, in the 12th line ''IRS'' should read ''IHS''.

2. On page 55123, in the first column, in the third full paragraph, seven lines from the bottom ''IRS'' should read ''IHS''.

[FR Doc. Z8–22359 Filed 10–6–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 23, 2008, 8 a.m. to October 24, 2008, 5 p.m., Holiday Inn Express Hotel and Suites, San Francisco Fisherman's Wharf, 550 North Point Street, San Francisco, CA, 91433 which was published in the **Federal Register** on September 19, 2008, 73 FR 54408–54411.

The meeting will be held October 22, 2008, 6 p.m. to October 23, 2008, 8 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: September 30, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–23594 Filed 10–6–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as