Consultant Services, Inc., requested that FDA determine whether PREVACID NAPRAPAC 250 was withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined previously, FDA has determined that TAP's PREVACID NAPRAPAC 250 was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, the agency notes that a higher strength of PREVACID NAPRAPAC 250 [PREVACID NAPRAPAC 500 (15 mg/500 mg)] is currently being marketed. In addition, the petitioner identified no data or information suggesting that PREVACID NAPRAPAC 250 was withdrawn from sale for reasons of safety or effectiveness. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records concerning the withdrawal, FDA found no indication that the decision not to commercially market PREVACID NAPRAPAC 250 was a result of any safety or effectiveness concerns regarding the product. Accordingly, the agency will continue to list PREVACID NAPRAPAC 250 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 PREVACID NAPRAPAC 250 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. E7–15233 Filed 8–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0125]

Determination That DEXEDRINE (Dextroamphetamine Sulfate) Oral Solution, 5 Milligrams per 5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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determined that DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 milligrams (mg) per 5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness.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 dextroamphetamine sulfate oral solution, 5 mg/5 mL.

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.

DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, is the subject of approved ANDA 83–902 held by GlaxoSmithKline (GSK). DEXEDRINE (dextroamphetamine sulfate) oral solution is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). GSK's ANDA 83–902 was originally approved in 1976 and was discontinued in 1988. Lachman Consultant Services, Inc., submitted a citizen petition dated March 17, 2006 (Docket No. 2006P–0125/CP1), under 21 CFR 10.30, requesting that the agency determine, as described in § 314.161, whether DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA has determined that GSK's DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that DEXEDRINE (dextroamphetamine sulfate) is available in an extended release capsule form and is a widely used product that has been marketed for many decades in many dosage forms. Neither the petition nor any comment to the petition identified evidence suggesting that DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was withdrawn for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA determines that GSK's DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DEXEDRINE (dextroamphetamine sulfate) oral

solution, 5 mg/5 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 DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, 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. E7–15236 Filed 8–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for ACTIQ (fentanyl), ALDARA (imiquimod), AMBIEN (zolpidem), COREG (carvedilol), PROVIGIL (modafinil), and ZYPREXA (olanzapine). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (the BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6460, Silver Spring, MD 20993–0002, 301–796–0700, e-mail: *grace.carmouze@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for ACTIQ (fentanyl), ALDARA (imiquimod), AMBIEN (zolpidem), COREG (carvedilol), PROVIGIL (modafinil), and ZYPREXA (olanzapine). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet at *http://www.fda.gov/cder/pediatric/index.htm* summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for ACTIQ (fentanyl), ALDARA (imiquimod), AMBIEN (zolpidem), COREG (carvedilol), PROVIGIL (modafinil), and ZYPREXA (olanzapine). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/pediatric/index.htm*.

Dated: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15234 Filed 8–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Poison Control Center Stabilization and Enhancement Grant Programs

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Response to solicitation of comments.

SUMMARY: A notice was published in the **Federal Register** (FR) on February 13, 2007, (Vol. 72, p. 6738–6739), describing HRSA's proposal to institute an exception to the Department of Health and Human Services' policy directive governing indirect cost recovery. The notice requested public comments on the proposed exception to Departmental policy requirements to be sent to HRSA no later than March 15, 2007.

Three comments were received, one from a Poison Control Center (PCC) host institution (grant recipient) and two from individual PCCs. Two of the three commenters supported HRSA's plan to institute an exception from the grants policy directive, which would permanently limit indirect cost recovery to 10 percent for the Poison Control Center Stabilization and Enhancement Grant Programs.

Issue: Institution of a 10 Percent Limit on the Indirect Cost

Comments: Two of the three commenters fully supported HRSA's proposal to permanently limit indirect cost recovery rates to 10 percent for this program. One commenter raised concern that the limitation would impose greater burdens on the host institution by shifting the unrecovered administrative costs to the host institution. In response, we replied that the 10 percent limitation had been in effect since the institution of the award program.

Agency Response: As noted in the referenced **Federal Register** Notice, since 2001, the HRSA Poison Control Program has limited indirect costs to 10 percent of the allowable total direct costs for grantees with negotiated rate agreements. This limitation on indirect costs was requested annually because many PCCs are housed within universities and hospitals (the official