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.

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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