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]

BILLING CODE 4160–01–S

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

grantees) which have established indirect cost rates in the range of 30 to 50 percent. Without a limitation on indirect cost rates, the objectives of the grant programs would not be met for the following reason:

The average amount of these grant awards has been approximately $200,000, with some amounts as low as $30,000. Depending upon the host institution's indirect cost rate, as much as 50 percent of the grant award could be consumed by the institution's indirect costs, thus significantly reducing the amount of funds available to initiate and maintain the activities of the grant.

Given the adverse impact on grant activities for this program if full indirect cost recovery were permitted, and that comments received were generally favorable to HRSA's proposal, HRSA is instituting the 10 percent limitation for the Poison Control Center Stabilization and Enhancement Grant Programs.

FOR FURTHER INFORMATION CONTACT: Maxine Jones at *mjones@hrsa.gov.,* Health Resources and Services Administration, Healthcare Systems Bureau, Poison Control Program.

Dated: July 30, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–15352 Filed 8–6–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on January 1, 2007, through March 31, 2007.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by'' one of the vaccines referred to in the Table, or

(b) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Division of Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Stacey Heinzelman, Milwaukee, Wisconsin, Court of Federal Claims Number 07–0001V.

2. Wilma Fagio, Monroe, North Carolina, Court of Federal Claims Number 07–0005V.

3. Norma and Douglas Rosenberg on behalf of Kevin Rosenberg, Lake Success, New York, Court of Federal Claims Number 07–0009V.

4. Annie Bell, Greensboro, North Carolina, Court of Federal Claims Number 07–0011V.

5. Anthony Nevels, Aurora, Illinois, Court of Federal Claims Number 07–0019V.

6. Louise Schmidt, Cherry Hill, New Jersey, Court of Federal Claims Number 07–0020V.

7. Shemeka Ramsey on behalf of Demarius Jamar Ramsey, Deceased, Columbia, South Carolina, Court of Federal Claims Number 07–0021V.