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.

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 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.

FOR FURTHER INFORMATION CONTACT:
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