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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier N. Hawkins

[Docket No. FDA-2008-N-0324]

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 ABILIFY (aripiprazole), ANDROGEL (testosterone), and DIOVAN (valsartan). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act, enacted in 2002, (the 2002 BPCA). For all pediatric supplements submitted under the 2002 BPCA, the 2002 BPCA required FDA to make available to the public, including by publication in the **Federal Register**, 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, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. 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

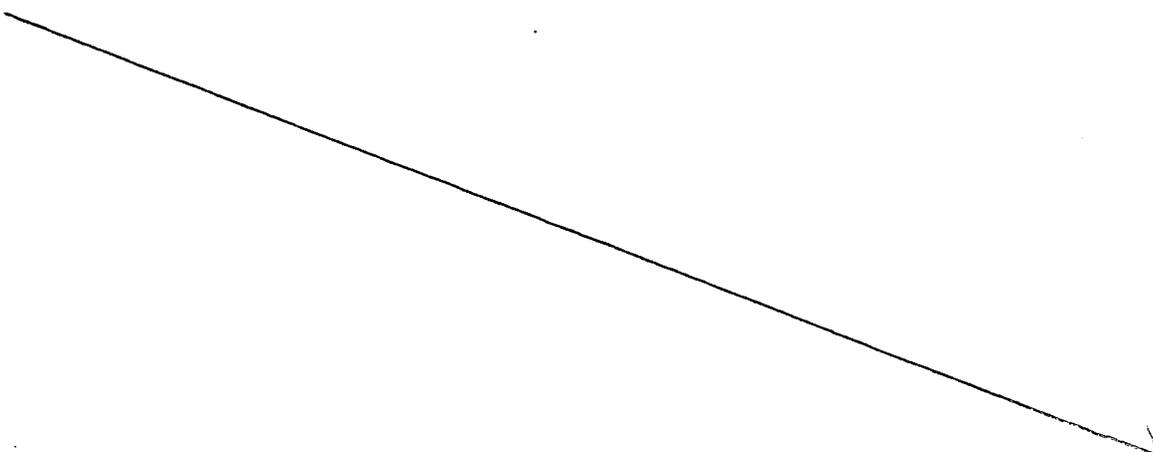
FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for ABILIFY (aripiprazole), ANDROGEL (testosterone), and DIOVAN (valsartan). The summaries are being made available consistent with section 9 of the 2002 BPCA (Public Law 107-109). Enacted on January 4, 2002, the 2002 BPCA reauthorized, 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 2002 BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the 2002 BPCA, the 2002 BPCA required FDA to make available to the public, including by publication in the **Federal Register**, a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement within 180 days of study submission to FDA (21 U.S.C. 355a(j)(1)).

The pediatric exclusivity program described in section 505A of the act again was reauthorized on September 27, 2007, in title V of the Food and Drug

Administration Amendments Act (FDAAA) (Public Law 110–85). FDAAA revised the public dissemination provision previously found in 21 U.S.C. 355a(j)(1). As revised, not later than 210 days after the date of submission of a report on a pediatric study conducted under the pediatric exclusivity program, FDA must make available to the public the medical, statistical, and clinical pharmacology reviews of the pediatric studies (21 U.S.C. 355a(k)(1)). Under FDAAA, publication in the **Federal Register** is no longer required. FDA currently posts these reviews on the Internet at http://www.fda.gov/cder/pediatric/BpcaPrea_full_review.htm.

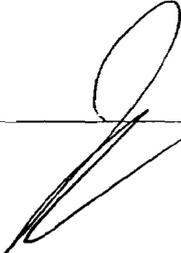
The three sets of summaries being announced in this issue of the **Federal Register** are the last summaries of reviews of supplements subject to the 2002 BPCA dissemination provision. Because publication in the **Federal Register** is no longer required, this will be the last notice announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted under the pediatric exclusivity program. 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 ABILIFY (aripiprazole), ANDROGEL (testosterone), and DIOVAN (valsartan). 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: 6/3/08
June 3, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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Dawn P. Hawkins