biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human biologic product ROTATEQ (Rotavirus Vaccine, Live, Oral, Pentavalent). ROTATEQ is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3, and G4, when administered as a 3-dose series to infants between the ages of 6 to 32 weeks. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ROTATEQ (U.S. Patent No. 5,626,851) from the Wistar Institute of Anatomy and Biology and the Children's Hospital of Philadelphia, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 28, 2007, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ROTATEQ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ROTATEQ is 4,577 days. Of this time, 4,272 days occurred during the testing phase of the regulatory review period, while 305 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: July 26, 1993. The applicants claim June 18, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 26, 1993, when the IND was removed from clinical hold and studies in humans could proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: April 5, 2005. FDA has verified the applicants' claim that the biologics license application (BLA) for ROTATEQ (BLA 125122) was initially submitted on April 5, 2005.

3. *The date the application was approved*: February 3, 2006. FDA has verified the applicants' claim that BLA 125122 was approved on February 3, 2006.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, these applicants seek 1,751 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 11, 2008. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 8, 2008. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 21, 2008.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E8–13109 Filed 6–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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: June 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–13099 Filed 6–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HIV/AIDS Bureau; Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is amending the uniform waiver standards for Ryan White HIV/AIDS Program grantees requesting a core medical services waiver for fiscal year (FY) 2009 and beyond. Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program), requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS identified and eligible under the legislation. HRSA has issued waiver standards for grantees under Parts A, B, and C of Title XXVI of the PHS Act. This **Federal Register** notice seeks to make public the final notice of Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C effective FY 2009.

SUPPLEMENTARY INFORMATION: The Ryan White HIV/AIDS Program imposes two criteria for waiver eligibility: (1) no waiting lists for AIDS Drug Assistance Program (ADAP) services; and (2) core medical services availability within the relevant service area to all individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. (See sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act.) HRSA's HIV/AIDS Bureau issued interim waiver eligibility guidance for FY 2007 to provide immediate implementation of these waiver provisions. The final Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C reflects modifications based on public comment received in response to the guidance published in the **Federal Register** on November 27, 2007. During the 30-day comment period ending December 26, 2007, HAB received comments from the public.

Beginning in FY 2009, HRSA will utilize new standards for granting waivers of the core medical services requirement for Ryan White HIV/AIDS Program grantees. These standards meet the intent of the Ryan White HIV/AIDS Treatment Modernization Act of 2006 to increase access to core medical services, including antiretroviral drugs, for persons with HIV/AIDS and to ensure that grantees receiving waivers demonstrate the availability of such services for individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. The purposes of this notice are: (1) To establish a uniform standard for core medical services waiver eligibility for grantees under Parts A, B, and C of Title XXVI of the PHS Act; and (2) to establish a process for waiver request submission, review and notification. The core medical services waiver uniform standard and waiver request process in this notice apply to Ryan White HIV/AIDS Program grant awards under Parts A, B, and C of Title XXVI of the PHS Act effective for the FY 2009 grant year.

Comments on the Proposed Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C

There were several public comments in strong support of the draft policy stating that the proposed changes allow more funds to be allocated to life-saving core medical services, including medications. The following suggestions and concerns were the main issues raised in the public comments.

Issue (1): Types of Documentation and Evidence Required as Part of the Waiver Request.

(Comment) Submission of documentation letters from private payers should be optional, not required.

(Response) HRSA concurs with the suggestion and changed the sentence regarding private insurers to ''letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers''.