issues: (1) Measures; (2) data collection and validation; (3) incentive structure; and (4) public reporting. It is also charged with preparing a set of design options, narrowing the set of design options to prepare a draft plan, and preparing a report on the plan for implementing VBP for Medicare hospital services, which will be provided to the Congress as required under section 5001(b)(3) of the DRA.

In the November 24, 2006 **Federal Register**, we announced that we would have a listening session to consider design questions posed in the Issues Paper that we posted on our Web site *http://www.cms.hhs.gov.* This listening session was held on January 17, 2007.

II. Listening Session Format and Agenda

The second listening session will be held on April 12, 2007 to consider the Draft Plan. This listening session will begin at 10 a.m. with an overview of the objectives for the session and a brief summary of the approach to developing the Draft Plan. Beginning at approximately 10:30 a.m., the remainder of the meeting will be devoted to addressing each section of the Plan. The agenda will provide opportunities for brief 2-minute comments from on-site session attendees. As time allows, telephone participants will also have the opportunity to provide brief 2-minute comments. A lunch break will occur from approximately 12:30 p.m. to 1:30 p.m. The meeting will conclude by 5 p.m. with brief comments on ''next steps.''

III. Registration Instructions

Persons interested in attending the meeting or listening by teleconference must register by completing the on-line registration located at *http://registration.mshow.com/cms2/.* The on-line registration system will generate a confirmation page to indicate the completion of your registration. Please print this page as your registration receipt.

Individuals may also participate in the listening session by teleconference. Registration is required. The call-in number will be provided upon confirmation of registration.

An audio download of the listening session will be available through the CMS Hospital Center Web site within 72 hours after completion of the listening session.

IV. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on April 9, 2007. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 550 registrants.

The on-site check-in for visitors will begin at 9:15 a.m. Please allow sufficient time to go through the security checkpoints at both the entrance to the grounds and the entrance to the building. It is suggested that you arrive at central building by 9 a.m. so that you will have enough time to check-in before the session begins.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must check in by name with Security, provide a government-issued ID, and pass through a metal detector. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, including items such as laptops, cell phones, and palm pilots, are subject to physical inspection.

Authority: Section 5001(b) The Deficit Reduction Act (DRA) of 2005.

Dated: February 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–3048 Filed 2–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0261]

Determination of Regulatory Review Period for Purposes of Patent Extension; EXJADE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EXJADE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the 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 drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product EXJADE (deferasirox). EXJADE is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EXJADE (U.S. Patent No. 6,465,504) from Novartis AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of

EXJADE represented the first permitted commercial marketing or use of the product. 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 EXJADE is 2,288 days. Of this time, 2,103 days occurred during the testing phase of the regulatory review period, while 185 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 (the act) (21 U.S.C. 355) became effective*: July 31, 1999. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 31, 1999.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: May 2, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for EXJADE (NDA 21–882) was initially submitted on May 2, 2005.

3. *The date the application was approved*: November 2, 2005. FDA has verified the applicant's claim that NDA 21–882 was approved on November 2, 2005.

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, this applicant seeks 648 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 April 24, 2007. 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 August 22, 2007. 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.

Dated: February 3, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–3041 Filed 2–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0356]

Determination of Regulatory Review Period for Purposes of Patent Extension; BARACLUDE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BARACLUDE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the 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 drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product BARACLUDE (entecavir). BARACLUDE is indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases or histologically active disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BARACLUDE (U.S. Patent No. 5,206,244) from Bristol-Myers Squibb Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 5, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BARACLUDE 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 BARACLUDE is 2,993 days. Of this time, 2,811 days occurred during the testing phase of the regulatory review period, while 182 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 Cosmetics Act (the act) (21 U.S.C. 355(i)) became effective*: January 19, 1997. FDA has verified the applicant's