3. Approve and disapprove contract proposals for award, not including proposals for national interim grantee contracts.

4. Approve and disapprove quality improvement plans (QIP) as required under 42 U.S.C. 9836A(d)(2)(B).

5. Conduct, as the responsible HHS official, informal meetings with current grantees or current or prospective delegate agencies as authorized by 45 CFR part 1303.11 and 1303.12.

6. Conduct, as the responsible HHS official, informal meetings authorized by 45 CFR part 1303.21 related to appeals by current or prospective delegate agencies.

7. Serve as the Approving Official to sign audit determination letters only where resolution does not involve a cost disallowance.

8. Approve and issue termination and suspension actions resulting from monitoring review reports approved and issued by the Regional Office.

(b) Limitations

1. The approval of grant applications requires concurrence of the appropriate Grants Officer.

2. The approval of contract proposals and awards are subject to the requirements of the Federal Acquisition Regulations and require consultation with the Director, Office of Head Start and the concurrence of the Contracting Officer.

3. The approval and issuance of terminations and suspensions resulting from monitoring review reports approved and issued by the Regional Office require the concurrence of the Director, Office of Head Start.

4. This redelegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

5. Any redelegation shall be in writing and prompt notification must be provided to all affected managers, supervisors, and other personnel, and requires the concurrence of the Deputy Assistant Secretary for Administration.

(c) Effective Date

This redelegation was effective on April 26, 2007.

(d) Effect on Existing Delegations

This redelegation of authority supersedes all previous delegations from the Director, Office of Head Start, on these subjects.

I hereby affirm and ratify any actions taken by the Director, Program Operations Division which, in effect, involved the exercise of these authorities prior to the effective date of this redelegation.

Dated: May 15, 2007.

Channell Wilkins,

Director, Office of Head Start.

[FR Doc. E7–9925 Filed 5–22–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegation of Authority

Notice is hereby given that I have redelegated to the Regional Program Managers, American Indian Alaska Native Program Branch Chief, and Migrant and Seasonal Program Branch Chief, Office of Head Start, the following authorities vested in me by the Director, Office of Head Start, in the memoranda dated April 26, 2007.

(a) Authorities Delegated

1. Approve and disapprove refunding and supplemental funding applications for existing grantees, not including designated interim grantees.

2. Approve and disapprove collaboration grant applications authorized under 42 U.S.C. 9835.

3. Approve and disapprove contract proposals for award, not including proposals for national interim grantee contracts.

4. Approve and disapprove quality improvement plans (QIP) as required under 42 U.S.C. 9836A(d)(2)(B).

5. Conduct, as the responsible HHS official, informal meetings with current grantees or current or prospective delegate agencies as authorized by 45 CFR 1303.11 and 1303.12.

6. Conduct, as the responsible HHS official, informal meetings authorized by 45 CFR part 1303.21 related to appeals by current or prospective delegate agencies.

7. Serve as the Approving Official to sign audit determination letters only where resolution does not involve a cost disallowance.

8. Approve and issue termination and suspension actions resulting from monitoring review reports approved and issued by the Regional Office.

(b) Limitations

1. The approval of grant applications requires concurrence of the appropriate Grants Officer.

2. The approval of contract proposals and awards are subject to the requirements of the Federal Acquisition Regulations and require consultation with the Director, Office of Head Start and the concurrence of the Contracting Officer.

3. The approval and issuance of terminations and suspensions resulting from monitoring review reports approved and issued by the Regional Office require the concurrence of the Director, Office of Head Start.

4. This redelegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

5. Any redelegation shall be in writing and prompt notification must be provided to all affected managers, supervisors, and other personnel, and requires the concurrence of the Deputy Assistant Secretary for Administration.

(c) Effective Date

This redelegation was effective on April 26, 2007.

(d) Effect on Existing Delegations

This redelegation of authority supersedes all previous delegations from the Director, Office of Head Start, on these subjects.

I hereby affirm and ratify any actions taken by any Regional Program Manager, the American Indian Alaska Native Program Branch Chief or the Migrant and Seasonal Program Branch Chief which, in effect, involved the exercise of these authorities prior to the effective date of this redelegation.

Dated: May 14, 2007.

Renee Perthuis,

Director, Program Operations Division.

[FR Doc. E7–9928 Filed 5–22–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0260]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ORENCIA 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

which claims that human biological 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–007), 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological 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 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 recently approved for marketing the human biological product ORENCIA (abatacept). ORENCIA is indicated for reducing signs and symptoms, inducing major clinical response, slowing the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease modifying anti-rheumatic drugs, such as methotrexate or TNF antagonists. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ORENCIA (U.S. Patent No. 5,851,795) from Bristol-Myers Squibb Company, 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 biological product had undergone a regulatory review period and that the approval of ORENCIA 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 ORENCIA is 3,803 days. Of this time, 3,536 days occurred during the testing phase of the regulatory review period, while 267 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 28, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 28, 1995.

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 1, 2005. The applicant claims March 31, 2005, as the date the biologics license application (BLA) for ORENCIA (BLA 125118) was submitted. However, FDA records indicate that BLA 125118 was received on April 1, 2005.

3. *The date the application was approved*: December 23, 2005. FDA has verified the applicant's claim that BLA 125118 was approved on December 23, 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 1,414 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 July 23, 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 November 19, 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: May 2, 2007

Jane A. Axelrad,

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

[FR Doc. E7–9945 Filed 5–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0501]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GARDASIL 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 which claims that human biological product.

ADDRESSES: Submit written or electronic 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–007), Food and Drug