appreciate the public's assessment of whether: (1) The policy issues identified in the draft report are appropriately focused; (2) any policy issues have been overlooked; and, (3) the issues are organized in appropriate categories and addressed in such a way as to give policy makers sufficient understanding of why the issue is important. In addition, the committee would value feedback on the sections of the draft report that discuss the importance of public engagement and the mechanisms that could be employed to achieve such engagement.

SACGHS will be able to consider comments received by July 31, 2006, as it prepares its final report. The report and public comments will be discussed at a future SACGHS meeting.

Comments will be available for public inspection at the NIH Office of Biotechnology Activities Monday through Friday between the hours of 8:30 a.m. and 5 p.m.

Dated: June 2, 2006.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. E6–9136 Filed 6–12–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration for Native Americans

AGENCY: Administration for Native Americans, Administration for Children and Families, HHS.

ACTION: Award announcement.

SUMMARY: The Administration for Native Americans (ANA) herein announces a Program Expansion Supplement to the Red Lake Band of Chippewa Indians, Red Lake, Minnesota. This supplement for $136,400 will extend funding for 11 youth volunteers through the second year of the project. In FY 2005, ANA provided an urgent grant award to the Tribe to assist in mitigating the effects of the tragic events of the school shooting in March 2005 that resulted in the death of students, faculty and staff. The shooting marked the highest death toll in U.S. school shootings since the Columbine High School massacre in April 1999.

Due to the devastation created by the high school shooting, ANA is providing urgent financial assistance for minor renovations to the local community centers to support positive community development; funding to hire 11 volunteers to assist youth and members of the community in coping with this event; and building support systems, which will aid in preventing future tragedies.

FOR FURTHER INFORMATION CONTACT: Sheila Cooper, Director of Program Operations, toll-free at 877–922–9262.

SUPPLEMENTARY INFORMATION: This award will be made pursuant to Section 803 of the Native American Programs Act of 1974.

Dated: June 7, 2006.

Kimberly Romine,

Deputy Commissioner, Administration for Native Americans.

[FR Doc. E6–9209 Filed 6–12–06; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0025]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INCRELEX 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 INCRELEX (mecasermin [rDNA origin] injection). INCRELEX is indicated for the long-term treatment of growth failure in children with severe primary IGF–1 deficiency (Primary IGFD) or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INCRELEX (U.S. Patent No. 5,681,814) from Genentech, Inc., 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 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 INCRELEX 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 INCRELEX is 4,828 days. Of this time, 4,644 days occurred during the testing phase of the regulatory review period, while 184 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(i)) became effective*: June 13, 1992. The applicant claims June 16, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 13, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: February 28, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for Increlex (NDA 21–839) was initially submitted on February 28, 2005.

3. *The date the application was approved*: August 30, 2005. FDA has verified the applicant's claim that NDA 21–839 was approved on August 30, 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 1,058 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 14, 2006. 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 11, 2006. 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 17, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–9138 Filed 6–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0026]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LUVERIS 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 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–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 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 drug 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 LUVERIS (lutropin alfa). LUVERIS, concomitantly administered with follitropin alfa for injection, is indicated for stimulation of follicular development in infertile hypogonadotropic hypogonadal women with profound luteinizing hormone deficiency. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LUVERIS (U.S. Patent No. 5,639,639) from Genzyme Corp., 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 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 LUVERIS 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 LUVERIS is 3,927 days. Of this time, 2,670 days occurred during the testing phase of the regulatory review period, while 1,257 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(i)) became effective*: January 9, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 9, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: May 1, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for Luveris