DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator; American Health Information Community Biosurveillance Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the sixth of the American Health Information Community Biosurveillance Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.)

DATES: June 22, 2006 from 1 p.m. to 3 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090.

FOR FURTHER INFORMATION CONTACT: *http://www.hhs.gov/healthit/ahic/bio_main.html.*

SUPPLEMENTARY INFORMATION: The meeting will be available via Web cast as *http://www.eventcenterlive.com/cfmx/ec/login/login1.cfm?BID=67.*

Kathryn Barr,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator.

[FR Doc. 06–5335 Filed 6–12–06; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Genetics, Health, and Society; Request for Public Comment

AGENCY: Office of the Secretary, HHS.

ACTION: A request for public comment on a draft report to the Secretary of Health and Human Services on policy issues raised by the prospect of a U.S. large population cohort project for the study of genetic variation, the environment, and common disease.

SUMMARY: The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is requesting public comment on a draft report on policy issues raised by the prospect of the U.S. undertaking a large population cohort project for the study of genes, environment, and disease. A copy of the report, ''Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease,'' is available electronically at *http://www4.od.nih.gov/oba/sacghs/public_comments.htm.* A copy may also be obtained from the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) by e-mailing Ms. Amita Mehrotra at *mehrotraa@od.nih.gov* or calling 301–496–9838.

DATES: In order for public comments to be considered by SACGHS in finalizing its report to the Secretary, the public is asked to submit comments by July 31, 2006.

ADDRESSES: Public comments on the draft report should be addressed to Reed V. Tuckson, M.D., Chair, SACGHS, and transmitted to SACGHS via an e-mail to Ms. Mehrotra at *mehrotraa@od.nih.gov.* Comments may also be submitted by mailing or faxing a copy to NIH OBA at 6705 Rockledge Drive, Suite 750, Bethesda, MD, 20892 NIH OBA's fax number is 301–496–9839.

FOR FURTHER INFORMATION CONTACT: Ms. Amita Mehrotra, NIH OBA, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838, *mehrotraa@od.nih.gov.*

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. For more information about the Committee, please visit its Web site: *http://www4.od.nih.gov/oba/sacghs.htm.* In a 2004 priority-setting process, SACGHS determined that opportunities and challenges associated with conducting large population cohort studies aimed at understanding the relationships of genes, the environment, and common, complex diseases warranted in-depth study. A large population initiative raises many policy issues for a number of reasons, including: (1) It will involve an unprecedented number of people (500,000 to 1,000,000 or more individuals) and, thereby, will have a significant public profile and a direct impact on many people; (2) it requires a relatively large investment of public resources and, as such, warrants deliberation and a broad consensus about the relative value to science, society, and the Nation; and (3) the nature of the information that will be derived from it raises ethical, legal, social and public policy concerns could be unique and/or significant, particularly in view of the number of potential participants.

NIH Director, Elias A. Zerhouni, M.D., specifically requested SACGHS's advice on the scientific, public, and ethical processes and pathways that might help NIH or HHS make decisions about undertaking such an effort. Dr. Zerhouni specified that the Committee could be most helpful to the Secretary by conducting an inquiry that includes the following steps:

- Step 1: Delineate the questions that need to be addressed in order for policymakers to determine whether the U.S. Government should undertake, in any form, a large population project to elucidate the influence of genetic variation and environmental factors on common, complex disease.
- Step 2: Explore the ways in which, or processes by which, the questions that are identified in Step 1 can be addressed, including the need for any intermediate research studies, pilot projects, or policy analysis efforts.
- Step 3: Taking into account the possible ways in which the questions could be addressed, determine which approaches are optimal and feasible and recommend a specific course of action for moving forward.

SACGHS has developed a draft report that summarizes its findings and conclusions relevant to the development of a large population research initiative in the United States. The report focuses on preliminary and intermediate questions, steps, and strategies in five areas that should be addressed before an informed decision can be made about whether the United States should undertake such a project. These five areas are: (1) Research policy; (2) research logistics; (3) regulatory and ethical issues; (4) public health implications of research results; and (5) social implications of research results. The report also identifies options for how these issues might be addressed. A central theme of the report is that decisions about such a project must take account of public views and attitudes and that public engagement must be sought in planning for and implementing a large population project.

In view of the wide range of public policy issues and questions raised in the draft report, SACGHS hopes to receive input from the wide range of individuals, communities and groups who may have an interest in whether a large population cohort project is undertaken in the U.S. These include but are certainly not limited to members of the general public and patient community; scientists in many fields but certainly genomics, environmental health, epidemiology, and public health; health professionals; bioethicists; and legal, public policy, and public engagement experts. Comments on any aspect of the draft report are welcome. In particular, the committee would

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: