inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

2. Program Personnel (30 Percent)

The extent to which the applicant has described (a) the qualifications, experience, and commitment of the principal investigator (or project director) and their ability to devote adequate time and effort to provide effective leadership; and (b) the qualifications and experience of program personnel, including demonstrated capability and experience in conducting the air monitoring, sampling, and modeling activities described under the recipient activities.

3. Applicant Capability and Coordination Efforts (20 Percent)

The extent to which the proposal has described (a) the capability of the applicant's administrative structure to foster successful scientific and administrative management of a study; and (b) the capability of the applicant to demonstrate an appropriate plan for interaction with other public health and environmental agencies.

4. Data Access (10 Percent)

The extent to which the proposal has demonstrated the capability of the applicant to access records that will be helpful in identifying facilities that are currently using diisocyanates.

5. Program Budget—(Not Scored)

The extent to which the budget is reasonable, clearly justified, and consistent with intended use of cooperative agreement funds.

6. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports (Attachment II)

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

4. Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–17 Peer and Technical Reviews of Final Reports of Health Studies—ATSDR
AR–18 Cost Recovery—ATSDR
AR–19 Third Party Agreements—ATSDR
AR–22 Research Integrity

I. Where To Obtain Additional Information

A complete copy of the announcement may be downloaded from CDC's home page on the Internet at: *http://www.cdc.gov* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Edna Green, Grants Management Specialist, Grants Management Branch, Procurement & Grants Office, Centers for Disease Control and Prevention, Announcement 02166, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone number (770) 488–2722, Email address: ecg4@cdc.gov.

For program technical assistance, contact: Curtis W. Noonan, PhD, Epidemiologist, Division of Health Studies, Agency for Toxic Substances and Disease Registry, Executive Park, Building 4, Suite 1300, Atlanta, GA 30305, Telephone (404) 498–0588, E-mail Address: *Cnoonan@cdc.gov;* Or Nelda Godfrey, Funding Resource Specialist, Division of Health Studies, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd., NE., Mail Stop E–31, Atlanta, GA 30333, Telephone (404) 498–0628, E-mail Address: *nag9@cdc.gov.*

Dated: June 11, 2002.

Edward J. Schultz,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

Attachment II—Semi-Annual Report

Semi-annual report should include:

1. A brief program description.

2. A listing of program goals and objectives accompanied by a comparison of the actual accomplishments related to the goals and objectives established for the period.

3. If established goals and objectives to be accomplished were delayed, describe both the reason for the deviation and anticipated corrective action or deletion of the activity from the project.

4. Other pertinent information, including the status of the program.

5. Measures of Effectiveness shall be a data requirement to be submitted with or incorporated into the semi-annual progress reports.

6. Financial recap of obligated dollars to date as a percentage of total available funds.

[FR Doc. 02–16090 Filed 6–25–02; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Study Team for the Los Alamos Historical Document Retrieval and Assessment Project

The Centers for Disease Control and Prevention(CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the following meeting.

Name: Public Meeting of the Study Team for the Los Alamos Historical Document Retrieval and Assessment Project.

Time and Date: 5 p.m.–7 p.m., July 10, 2002.

Place: Northern New Mexico Community College, Joseph Montoya Building, Espanola Campus, 921 Paseo de Onate, Espanola, New Mexico 87532.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with Department of Energy (DOE) and replaced by an MOU signed in 1996, the Department of

Health and Human Services (HHS) is given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 between the ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This Study Team is charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purposes of this meeting is to review the goals, methods, and schedule of the project, discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns and provide advice to CDC.

Matters to Be Discussed: Agenda items include a presentation from the National Center for Environmental Health (NCEH) and/or its contractor regarding the information gathering project that is underway. There will be time for public input, questions, and comments. All agenda items are subject to change as priorities dictate.

Contact Persons for Additional Information: Phillip Green, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, N.E. (E–39), Atlanta, GA 30333, telephone 404/498–1717, fax 404/498–1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: June 20, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–16089 Filed 6–25–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1402]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BETAXON 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 Commissioner 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 drug 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 Commissioner 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 BETAXON (levobetaxolol). BETAXON is indicated for lowering intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BETAXON (U.S. Patent No. 4,911,920) from Alcon Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 17, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BETAXON 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 BETAXON is 947 days. Of this time, 765 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 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: July 23, 1997. The applicant claims June 23, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 23, 1997, 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 of the act*: August 26, 1999. The applicant claims August 25, 1999, as the