either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the postmarketing study commitment, a schedule for completing the study commitment, and a characterization of the current status of the study commitment. The report must also provide an explanation of the postmarketing study commitment's status by describing briefly the postmarketing study commitment's progress. A postmarketing study commitment schedule is expected to include the actual or projected dates for the following: (1) Submission of the study protocol to FDA, (2) completion of patient accrual or initiation of an animal study, (3) completion of the study, and (4) submission of the final study report to FDA. The postmarketing study commitment status must be described in the annual report according to the following definitions:

- Pending: The study has not been initiated, but does not meet the criterion for delayed;
- Ongoing: The study is proceeding according to or ahead of the original schedule;
- Delayed: The study is behind the original schedule;
- Terminated: The study was ended before completion, but a final study report has not been submitted to FDA; or
- Submitted: The study has been completed or terminated, and a final study report has been submitted to FDA.

Databases containing information on postmarketing study commitments are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Information in this report covers any postmarketing study commitment that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including those required (e.g., to demonstrate clinical benefit of a product following accelerated approval) and those agreed to with the applicant. Information summarized in this report includes: (1) The number of applicants with open (uncompleted) postmarketing commitments, (2) the number of open postmarketing commitments, (3) the status of open postmarketing commitments as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports, (4) the status of concluded postmarketing studies as determined by FDA, and (5) the number of applications with open postmarketing commitments for which sponsors did not submit an annual report within 60 days of the anniversary date of U.S. approval.

Additional information about postmarketing study commitments made by sponsors to CDER and CBER are provided on FDA's Web site at *http://www.fda.gov/cder*. Like this notice, the site does not list postmarketing study commitments containing proprietary information. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. The numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site. This notice incorporates totals for all postmarketing study commitments in FDA databases, including those undergoing review for accuracy. The report in this notice will be updated annually while the Web site is updated quarterly (in January, April, July, and October).

II. Summary of Information From Postmarketing Study Progress Reports

This report summarizes the status of postmarketing commitments as of September 30, 2005. If a commitment did not have a schedule or a postmarketing progress report was not received, the commitment is categorized according to the most recent information available to the agency.

Data in table 1 of this document are numerical summaries generated from FDA databases. The data are broken out according to application type (NDAs/ANDAs or BLAs).

TABLE 1.—SUMMARY OF POSTMARKETING STUDY COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2005)

	NDAs/ANDAs (% of Total)	BLAs[1] (% of Total)
Applicants With Open Postmarketing Commitments	154	44
Number of Open Postmarketing Commitments	1,231	321
Status of Open Postmarketing Commitments		
• Pending	797 (65%)	118 (37%)
• Ongoing	231 (19%)	94 (29%)
• Delayed	28 (2%)	53 (17%)
• Terminated	3 (<1%)	0
• Submitted	172 (14%)	56 (17%)
Concluded Studies (October 1, 2004 Through September 30, 2005)	156	56
• Commitment Met	136 (87%)	41 (73%)
• Commitment Not Met	5 (3%)	0
• Study No Longer Needed or Feasible	15 (10%)	15 (27%)
Applications With Open Postmarketing Commitments With Annual Reports Due, but Not Submitted Within 60 Days of the Anniversary Date of U.S. Approval	170 (47%)[2]	37 (50%)

[1] On October 1, 2003, FDA completed a consolidation of certain products formerly regulated by the CBER into the CDER. The previous association of BLA reviews only with CBER is no longer valid; BLAs are now received by both CBER and CDER. Fiscal year (FY) statistics for CDER BLA postmarketing study commitments will continue to be counted under BLA totals in this table.

[2] The search strategy was improved for the FY 2005 report and may explain, in part, the increased number of applications categorized as having overdue annual reports. Note that this statistic counts all annual reports submitted more than 60 days after the anniversary date of U.S. approval as overdue, including reports that may have been submitted on a modified reporting schedule in accordance with prior FDA agreement. Of the applications categorized as having overdue annual reports using this definition, annual reports were subsequently submitted in FY 2005 for 170/170 (100 percent) of NDAs/ANDAs and 19/37 (51 percent) of BLAs.

Dated: February 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3019 Filed 3–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement

SUMMARY: In accordance with the National Environmental Policy Act, 42 U.S.C. 4321–4347, the NIH is issuing this notice to advise the public that an environmental impact statement will be

prepared for the Rocky Mountain Laboratories Campus Master Plan, Hamilton, Ravalli County, Montana.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief, Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2W64, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–8056; or e-mail *nihnepa@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: Rocky Mountain Laboratories (RML) is located on 33 acres in the City of Hamilton, a small community in southwestern Montana. The laboratory is a component of the National Institute of Allergy and Infectious Diseases (NIAID), which is one of the 27 Institutes or Centers that comprise the NIH, one of the world's largest biomedical research facilities and the Federal government's focal point for medical and behavioral research. RML conducts and supports research of infectious diseases and the human immune system, with an emphasis on vector-borne transmission of infectious diseases and prion diseases. RML's mission also includes biomedical research into diseases caused by the intentional release of biological agents into civilian populations, as well as advancing basic knowledge about biological agents. Total building space on the campus amounts to approximately 207,000 gsf. Approximately 260 people work at the RML site.

A Master Plan is an integrated series of documents that present in graphic, narrative, and tabular form the current composition of NIH campuses and the plan for their orderly and comprehensive development over a 20-year period. The plan provides guidance in coordinating the physical development of NIH campuses, including building locations, utility capacities, road alignments, parking facilities, and the treatment of open spaces. General design guidelines are also used to provide detailed guidance for the placement and design of physical improvements.

The proposed action is to develop a long-range physical master plan for RML. The plan will cover a 20-year planning period and address the future development of the RML site, including placement of future construction; vehicular and pedestrian circulation on- and off-campus; parking within the property boundaries; open space in and around the campus; required setbacks; historic properties; natural and scenic resources; noise; and lighting. The plan will examine potential growth in RML personnel, possible land acquisitions, and consequent construction of space over the planning period. Future construction on the site could include such facilities as new animal holding, research laboratories, and support facilities.

In accordance with 40 CFR parts 1500–1508 and DHHS environmental procedures, NIH will prepare an Environmental Impact Statement (EIS) for the proposed master plan. The EIS will evaluate the impacts of the master plan should development occur as proposed. Among the items the EIS will examine are the implications of the master plan on community infrastructure, including, but not limited to, utilities, storm water management, traffic and transportation, and other public services. To ensure that the public is afforded the greatest opportunity to participate in the planning and environmental review process, NIH in inviting oral and written comments on the master plan and related environmental issues.

The NIH will be sponsoring a public Scoping Meeting to provide individuals an opportunity to share their ideas on the master planning effort, including recommended alternatives and environmental issues the EIS should consider. The meeting is planned for 7 p.m. on March 23, 2006 at the Hamilton High School commons in Hamilton, Montana. All interested parties are encouraged to attend. NIH has established a 45-day public comment period for the scoping process. Scoping comments must be postmarked *no later than* April 18, 2006 to ensure they are considered. All comments and questions on the EIS should be directed to Valerie Nottingham at the address listed above, telephone 301–496–7775; fax 301–480–8056; or e-mail *nihnepa@mail.nih.gov.*

Dated: February 24, 2006.

Juanita Holler-Mildenberg,

FAIA, Acting Director, Office of Research Facilities Development and Operations, National Institutes of Health.

[FR Doc. 06–2015 Filed 3–2–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Use of Replicators in Gene Therapy

Mirit Aladjem, Cindy Tseng, Haiqing Fu and Lixin Wang (NCI).

U.S. Provisional Application No. 60/715,113 filed 07 Sep 2005 (HHS Reference No. E–309–2005/0–US–01).

Licensing Contact: Susan Carson, D. Phil.; 301/435–5020; *carsonsu@mail.nih.gov.*

There remains a need for a gene therapy vector capable of delivering a stably maintained, appropriately-regulated therapeutic transgene without adverse side effects. Lack of expression of a therapeutic transgene is still a major obstacle for gene therapy and the extent of transcriptional silencing of gene therapy vectors depends on their chromosomal location and on the presence of nearby heterochromatin. Most active genes replicate early during S phase, while transcriptional silencing correlates with late replication. The location of DNA replication initiation events on chromatin is affected by DNA sequences termed replicators, which interact with distal sequences to establish an epigenetic permissive state that directs the replication machinery to the replicator at a specific time during S phase. NIH researchers at the National Cancer Institute have now shown that inclusion of functional replicators in transgenes are able to prevent gene silencing, suggesting that replicator sequences have an important role in stabilizing gene expression patterns. The ideal gene delivery vector system would include functional elements that permit stable maintenance and long-term regulated transgene expression and the inclusion of replicators may be key