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 REMODULIN is 4,026 days. Of this time, 3,443 days occurred during the testing phase of the regulatory review period, while 583 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*: May 15, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 15, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: October 16, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for REMODULIN (NDA 21–272) was initially submitted on October 16, 2000.

3. The date the application was approved: May 21, 2002. FDA has verified the applicant's claim that NDA 21–272 was approved on May 21, 2002.

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 337 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 March 29, 2004. 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 July 27, 2004. 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: January 13, 2004.

**Jane A. Axelrad,**

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

[FR Doc. 04–1841 Filed 1–28–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Record of Decision—Construction and Operation of an Integrated Research Facility by the National Institutes of Health at Fort Detrick, MD

**AGENCY:** Department of Health and Human Services, National Institutes of Health (NIH) United States Army Garrison (USAG), Fort Detrick.

**ACTION:** Notice. The Department of Health and Human Services, NIH, and the United States Army Garrison, Fort Detrick (Cooperating Agency), have decided, after completion of a Final Environmental Impact Statement (EIS) and a thorough consideration of public comments on the Draft EIS, to implement Alternative I (Proposed Action), which was identified as the Preferred Alternative in the Final EIS. This action involves the construction and operation of an Integrated Research Facility (IRF) by NIH on a site adjacent to existing U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) facilities at Fort Detrick, Maryland.

The National Institute of Allergy and Infectious Diseases (NIAID), a component of NIH, will be the occupant of the facility, which will contain Intramural NIAID bio-safety level –2, –3, and –4 laboratory and animal research facilities for conducting biodefense and emerging infectious disease research. NIAID's biodefense mission is different but complementary to USAMRIID's. The selected action best satisfies NIH's needs and the biodefense research goals of NIAID and USAMRIID. Moreover, it fosters increased interagency collaboration between NIH and U.S. Army scientists by building on the already well established formal cooperation that exists between these two organizations. NIH will incorporate design and operational safeguards in the facility to protect laboratory workers and local residents from possible harmful effects related to the operation of the facility, however remote these occurrences may be. This action also allows NIH to address a critical national shortage in bio-safety level-4 (BSL–4) capability.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ronald Wilson, Master Planner, Division of Facilities Planning, ORF, National Institutes of Health, 31 Center Drive, Room 3B44, MSC 2162, Bethesda, Maryland, 20817–2162, telephone 301–496–5037, e-mail: *wilsoron@ors.od.nih.gov.*

**SUPPLEMENTARY INFORMATION:** The National Institutes of Health (NIH) and United States Army Garrison, Fort Detrick (USAG), have prepared this Record of Decision (ROD) on a Final EIS for the construction and operation of an Integrated Research Facility by NIH at Fort Detrick, Maryland. This ROD includes:

1. The final decision;

2. All alternatives considered, specifying the alternative or alternatives which were considered to be environmentally preferable;

3. A discussion of factors which were involved in the decision, including any essential considerations of national policy which were balanced in making the decision and a statement of how those considerations, if any, entered into the decision;

4. A statement of whether all practicable means to avoid or minimize potential environmental harm from the selected alternative have been adopted, and if not, why they were not;

5. A description of mitigation measures that will be undertaken to make the selected alternative environmentally acceptable;

6. A discussion of the extent to which pollution prevention is included in the decision and how pollution prevention measures will be implemented; and

7. A summary of any monitoring and enforcement program adopted for any mitigation measures.

**Alternatives Considered**

Two reasonable alternatives were identified and considered in the Final EIS. They are (1) Alternative I, the Proposed Action, and, (2) the No Action Alternative. The Proposed Action is described above. Under the No Action Alternative, NIH would not build the IRF thereby eliminating the negligible to minor adverse impacts associated with implementation of the selected action. Selection of the No Action alternative, however, would prevent NIH and the public from realizing the health and safety benefits that would derive from the research conducted in the planned IRF. This research will focus on disease-causing organisms that might emerge naturally or be used as agents of

bioterrorism as well as developing a better understanding of the pathogenesis of such microbes and the human response to them. The knowledge gained will be used to develop new and improved diagnostic tests, vaccines, and therapies to protect civilians.

Three additional alternatives were identified but rejected as not practical and, therefore, are not evaluated in detail in the Final EIS. These are: (1) Construction and Operation of an IRF by NIH at another location within Area A of Fort Detrick (Alternative III); (2) Construction and Operation of an IRF by NIH within Area B of Fort Detrick (Alternative IV); and (3) Construction and Operation of an IRF by NIH outside Fort Detrick (Alternative V). The rejected alternatives, along with the reasons for their elimination, are described in the Final EIS.

**Factors Involved in the Decision**

Several factors are involved in NIH's decision to proceed with the Proposed Action as the selected action.

Based on analyses in the Draft and Final EISs, the selected action best satisfies the project's Purpose and Need, which involves expanding NIH's research capability and, in particular, its BSL–4 laboratory capacity, to support research related to developing new and improved diagnostic tests, vaccines, and therapies for biodefense purposes, as well as attaining a better understanding of emerging infectious diseases. In addition, the action is consistent with NIH's mission, which is to serve as the nation's steward for medical and behavioral research. Furthermore, as noted above, it will facilitate greater cooperation between NIH and U.S. Army researchers in the area of biodefense research.

From an environmental perspective, the IRF will result in minor to negligible disruption to the physical and biological environment. In instances where unavoidable adverse environmental effects are anticipated, the potential adverse impacts will be mitigated through compliance with existing regulatory requirements, application of Best Management Practices (BMPs), and adherence to construction contract requirements. The action also is in accord with Fort Detrick's Installation Master Plan and conforms to USAG's planning and environmental policies. Operation of the IRF will not adversely impact City of Frederick residents. Security measures either exist or will be implemented for the project.

In terms of national considerations, Congress clearly intended that the research laboratory be built on Department of the Army land at Fort Detrick. As a result, it appropriated $105 million to construct the research building at Fort Detrick.

Although options to locate the IRF on alternate sites at Fort Detrick were also considered early on in the development of the Final EIS, these were considered less favorable in terms of collaboration by personnel from both agencies since the IRF would be further removed from USAMRIID facilities. In addition, placing the IRF in another portion of Area A or in Area B is not consistent with Fort Detrick land use planning and would be more distant from existing infrastructure support. Alternative V, which involved locating the IRF on a site outside of Fort Detrick, was eliminated from evaluation in the Final EIS during the scoping process since it was determined to be contrary to congressional intent. Furthermore, placing the IRF outside of Fort Detrick could require costly land acquisition and infrastructure development that could delay completion of the IRF by several years.

**Practicable Means To Avoid or Minimize Potential Environmental Harm from the Selected Alternative**

All practicable means to avoid or minimize adverse environmental effects from the selected action have been identified and incorporated into the action.

**Pollution Prevention**

In accordance with DHHS General Administration Manual Part 30, Environmental Protection (dated February 25, 2000), pollution prevention will be a major focus of the design, construction, and operation of the IRF. Pollution prevention measures incorporated in the selected action include:

- Reducing construction waste by recycling materials wherever possible;
- Applying BMPs during construction to minimize soil erosion and potential airborne particulate matter;
- Including new state-of-the-art energy efficient equipment in the facility to reduce the energy demand on Fort Detrick electrical systems;
- Rendering all contaminated or potentially contaminated medical waste noninfectious by a combination of chemical and physical (autoclaving) methods before disposal or transport off-site;
- Sterilizing laboratory wastewater within the laboratories and, secondarily, within the facility itself through chemical disinfection or steam sterilization methods before discharging wastewater into the Fort Detrick sanitary sewer system;
- Employing High Efficiency Particulate Air filters to capture small particles in laboratory exhaust air before venting the air to the outside; and
- Requiring that IRF activities comply with the NIH waste management policies, which emphasize source segregation, inactivation, source reduction, reuse, and recycling.

**Mitigation Measures**

During the preparation of the Final EIS several potential environmental issues associated with implementation of the Proposed Action were identified. These included land use (land disturbance), construction noise, transportation (traffic and parking), geology (potential sinkholes), water resources (sedimentation, stormwater management, water supply), plant and animal ecology (displacement of deer and/or bird species), air quality (fugitive dust during construction, increased pollutant emissions during operation, and increased vehicular emissions), historic and archaeological resources (potential impacts on National Register eligible properties), and pollution prevention/waste management (construction wastes and handling and disposal of waste generated during operation). These potential adverse impacts were deemed to be negligible to minor, and capable of being mitigated through compliance with existing regulatory requirements, application of BMPs, and adherence to construction contract requirements.

In addition, possible adverse health and safety impacts on laboratory workers in the proposed IRF and on nearby residents during the operational phase of the project were evaluated. The risks were deemed to be negligible to minor, and able to be mitigated through adherence to guidelines outlined in Biosafety in Microbiological and Biomedical Laboratories, a joint publication of the Centers for Disease Control and NIH, as well as other standards for safe operational practices.

**Monitoring and Enforcement Program for Mitigation Measures**

Since potential adverse impacts would be mitigated by compliance with existing regulatory requirements, application of BMPs, and adherence to construction contract requirements, existing regulatory reporting requirements and contract administration procedures will serve in lieu of a formal Monitoring and Enforcement Program.

**Conclusion**

Based upon review and careful consideration of the impacts identified

in the Final EIS, results of various environmental and hazard assessment studies conducted in conjunction with the Draft EIS; public comments received throughout the National Environmental Policy Act process, including comments on the Draft EIS and those provided during the required 30-day waiting period for the Final EIS; and other relevant factors, such as congressional intent, NIH and USAG, Fort Detrick, have decided to implement Alternative I, the Proposed Action, construction and operation of the IRF by NIH on a site adjacent to existing USAMRIID facilities at Fort Detrick, Maryland.

Dated: January 21, 2004.

**Stephen A. Ficca,**

*Director, Office of Research Services, National Institutes of Health.*

Dated: January 22, 2004.

**John E. Ball,**

*Colonel, MS, Deputy Installation Commander.*

[FR Doc. 04–1887 Filed 1–28–04; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

### OMB Control Number 1004–0132; Information Collection Submitted to the Office of Management and Budget Under the Paperwork Reduction Act

The Bureau of Land Management (BLM) has sent a request to extend the current information collection to the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). On February 10, 2003, the BLM published a notice in the **Federal Register** (68 FR 6758) requesting comment on this information collection. The comment period ended on April 11, 2003. BLM received no comments. You may obtain copies of the collection of information and related forms and explanatory material by contacting the BLM Information Collection Clearance Officer at the telephone number listed below.

The OMB must respond to this request within 60 days but may respond after 30 days. For maximum consideration your comments and suggestions on the requirements should be directed within 30 days to the Office of Management and Budget, Interior Department Desk Officer (1004–0132), at OMB–OIRA via facsimile to (202) 395–6566 or e-mail to *OIRA_DOCKET@omb.eop.gov.* Please provide a copy of your comments to the Bureau Information Collection Clearance Officer (WO–630), Bureau of Land Management, Eastern States Office, 7450 Boston Blvd., Springfield, Virginia 22153.

*Nature of Comments:* We specifically request your comments on the following:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;

2. The accuracy of our estimates of the information collection burden, including the validity of the methodology and assumptions we use;

3. Ways to enhance the quality, utility and clarity of the information we collect; and

4. Ways to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

*Title:* Geothermal Leasing Reports and Resource Leasing and Drilling Operations (43 CFR 3200 and 3260).

*OMB Control Number:* 1004–0132.

*Bureau Form Number(s):* 3260–2, 3260–3, 3260–4, and 3260–5.

*Abstract:* The Bureau of Land Management (BLM) collects and uses the information from entities interested in the development of geothermal resources on public lands. Also, we collect and use information from geothermal lessees to determine if the lessee qualifies for lease extensions. We collect non-form information to determine if a lessee is making diligent and bona fide efforts to utilize and produce geothermal resources.

*Frequency:* Occasional, annual, 5-year, monthly, and nonrecurring.

*Description of Respondents:* Lessees and operators of Federal geothermal leases and Indian geothermal contracts subject to BLM oversight.

*Estimated Completion Time:* 1 to 10 hours depending on the form filed and 2 hours for each report submitted.

*Annual Responses:* 760 for the forms and 75 for reports.

*Application Fee Per Response:* 0.

*Annual Burden Hours:* 1,850.

*Bureau Clearance Officer:* Michael Schwartz, (202) 452–5033.

Dated: January 13, 2004.

**Michael H. Schwartz,**

*Bureau of Land Management, Information Collection Clearance Officer.*

[FR Doc. 04–1867 Filed 1–28–04; 8:45 am]

**BILLING CODE 4310–84–M**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[MT–926–04–1420–BJ]**

### Montana: Filing of Plats of Amended Protraction Diagrams

**AGENCY:** Bureau of Land Management, Montana State Office, Interior.

**ACTION:** Notice of filing of plats of amended protraction diagrams.

**SUMMARY:** The Bureau of Land Management (BLM) will file the plats of the amended protraction diagrams of the lands described below in the BLM Montana State Office, Billings, Montana, (30) days from the date of publication in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Brockie, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, P.O. Box 36800, Billings, Montana 59107–6800, telephone (406) 896–5125 or (406) 896–5009.

**SUPPLEMENTARY INFORMATION:** The amended protraction diagrams were prepared at the request of the U.S. Forest Service and are necessary to accommodate Revision of Primary Base Quadrangle Maps for the Geometronics Service Center.

The lands for the prepared amended protraction diagrams are:

**Principal Meridian**

Montana

Tps. 25, 26, 27, and 28 N., Rs. 17, 18, and 19 W.

The plat, representing the Amended Protraction Diagram 38 Index of unsurveyed Townships 25, 26, 27, and 28 North, Ranges 17, 18, and 19 West, Principal Meridian, Montana, was accepted October 10, 2003.

T. 25 N., R. 17 W.

The plat, representing Amended Protraction Diagram 38 of unsurveyed Township 25 North, Range 17 West, Principal Meridian, Montana, was accepted October 10, 2003.

T. 26 N., R. 17 W.

The plat, representing Amended Protraction Diagram 38 of unsurveyed Township 26 North, Range 17 West, Principal Meridian, Montana, was accepted October 10, 2003.

T. 27 N., R. 17 W.

The plat, representing Amended Protraction Diagram 38 of unsurveyed Township 27 North, Range 17 West, Principal Meridian, Montana, was accepted October 10, 2003.

T. 28 N., R. 17 W.

The plat, representing Amended Protraction Diagram 38 of unsurveyed Township 28 North, Range 17 West, Principal Meridian, Montana, was accepted October 10, 2003.