Special Reporting Requirements: Programmatic Reports and Financial Reports are required semi-annually. All required reports must be submitted in a timely manner, in recommended formats (to be provided), and the final report must also be submitted on disk or electronically using a standard word-processing program.

VII. Agency Contacts

Program Office Contact: April Myers, Program Specialist, 370 L'Enfant Promenade, SW., Washington, DC 20447. Phone: (202) 690–5985, TTY/TDD: (202) 690–6415, e-mail: *amyers@acf.hhs.gov*, fax: (202) 205–8037.

Grants Management Office Contact: Lois Hodge, Grants Officer, 370 L'Enfant Promenade, SW., Washington, DC 20447, (202) 401–2344, e-mail: *lhodge@acf.hhs.gov.*

VIII. Other Information

http://www.acf.hhs.gov/programs/add/.

Dated: June 7, 2004.

Patricia A. Morrissey,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 04–13509 Filed 6–16–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Integrated Research Facility Record of Decision

ACTION: Notice.

SUMMARY: The Department of Health and Human Services, The National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (EIS) and a thorough consideration of public comments on the Draft EIS and Supplemental Draft EIS, to implement the Proposed Action, which is identified as the Preferred Alternative in the Final EIS. This action involves construction and operation of an Integrated Research Facility and associated infrastructure improvements by the NIH at the Rocky Mountain Laboratories campus in Hamilton, Montana.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief of the Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities Development and Operations, NIH, Building 13, Room 2W64, 9000 Rockville Pike, Bethesda, MD 20892, telephone 301–496–7775, Fax 301–480–8056, e-mail *orsrmleis-r@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement (FEIS), Rocky Mountain Laboratories (RML), Integrated Research Facility, dated May 2004, and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

Selected Alternative

The NIH plans to construct an Integrated Research Facility (IRF) to expand the research capability of RML. Research to be conducted within the IRF includes infectious disease pathogenesis and immune response studies, development of candidate vaccines, diagnostic reagents and assays and therapeutic approaches. This work will focus and build upon RML's strength in vector-borne disease research. The RML does not and will not conduct research to develop offensive-biological weapons.

The IRF will contain Biosafety Level (BSL)–2, BSL–3, and BSL–4 laboratories, animal research facilities, administrative support offices, conference rooms, and break areas at RML in Hamilton, Montana. The facility would encompass approximately 105,000 square feet of building constructed within the existing 33-acre RML campus in the southwest portion of Hamilton.

The Integrated Research Facility and research programs would require additions and upgrades to the existing RML campus, including:

- A new chilled water plant and emergency power backup system;
- A new addition to Boiler Building 26 to house a new natural gas-fired boiler; and
- Construction of below grade systems and utility distribution tunnels to service the Integrated Research Facility.

The BSL–4 laboratory would be constructed within the Integrated Research Facility to provide the highest possible level of protection for scientists and the public. The BSL–4 laboratory would be located within the central core of the Integrated Research Facility, surrounded by a corridor that serves as a buffer between the laboratory and the exterior. Specially designed mechanical ventilating systems assure that negative pressure will be maintained for containment purposes. Other containment design features such as positive pressure sealed doors and airlocks will also be employed to assure containment. All effluent and emissions from the proposed laboratory would be treated in accordance with stringent, state of the art standards and practices. A facility operations manual, developed specifically for the integrated research facility, will be prepared and adopted prior to operation of the laboratory. Stringent safeguards, including engineering and design features and rigorous adherence to procedural requirements are necessary in BSL–3 and BSL–4 laboratory facilities to protect workers and prevent release of pathogens into the environment. Additionally, areas for the secure storage of pathogens will be provided.

Alternatives Considered

The NIH considered the two reasonable alternatives identified and considered in the FEIS: (1) The Proposed Action Alternative (now the selected alternative) and (2) the No Action Alternative (not constructing the Integrated Research Facility). Other alternatives considered but eliminated from detailed analysis included constructing the Integrated Research Facility at the NIH Campus in Bethesda, Maryland; constructing it at some other location outside RML; moving RML to a less populated area; and constructing and administering an Integrated Research Facility by another agency or at another National Institutes of Health facility. Based on the Purpose and Need for the project and environmental consequences of the Proposed Action, only the No Action Alternative was considered in detail and effects analysis documented. The other alternatives were considered, but not given detailed study. They did not meet the Purpose and Need of the Proposed Action (FEIS page 2–17).

Factors Involved in the Decision

Several factors were involved in the NIH's decision to proceed with the Proposed Action. Based on analyses in the Draft EIS, Supplemental Draft EIS, and Final EIS, the Proposed Action best satisfies the stated Purpose and Need, which is ''to provide a highly contained and secure intramural laboratory dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents.'' Because of its traditional strengths in the area of vector-borne infectious disease research and the federal funding parameters associated with National Institute of Allergy and Infectious Diseases' (NIAID)

intramural research program, the Integrated Research Facility is proposed to be located at RML.

The President and the Congress expanded the NIAID's mission to include basic and applied research aimed at addressing specific issues outlined in the national bio-defense response plans. The RML in Hamilton, Montana is the proposed location for a new high containment research facility because of the RML's historic strengths. The long, distinguished, and continuing history of RML in vector-borne agents would facilitate and expedite research on these agents. To achieve these expanded research goals, scientists at RML need additional laboratory facilities, particularly those that provide the appropriate environment to work on certain high consequence pathogens and emerging infectious disease agents.

The type of research proposed for the Integrated Research Facility fits precisely with expertise at RML. Part of the biodefense research plan is to study vector-borne (tick and flea) agents. The long, distinguished, and ongoing history of RML in this area will facilitate and thus expedite research on agents of this type. The level of expertise in this area at RML is unmatched at any other possible site. The unparalleled scientific climate at RML has for over 100 years fostered superior dedication and technical expertise in combating infectious and re-emerging infectious diseases. From the discovery of the causative agents of Rocky Mountain Spotted Fever by Dr. Howard Rickets and Lyme Disease by Dr. Willy Burgdorfer to the development of a plague vaccine, which proved to be 100% effective, the RML has been and is one of the world's premier research laboratories.

Integration of new BSL–3 and BSL–4 laboratories into the current RML facility provides the most benefit from the public monies to be invested and provides additional benefit in terms of the time it will take to provide functioning high and maximum containment laboratories in which to conduct the needed research invested. Fulfillment of the research mandate requires timely and effective response to the threats of emerging and re-emerging infectious diseases and bioterrorism, which is facilitated by building on the available scientific resources and research infrastructure present at RML. Relocation of the RML scientific community, if even possible, would result in years of unacceptable delay while duplicating the infrastructure already present at RML. Replicating the specialized laboratory facility to maintain the colonies and collections of the insect vectors necessary for support of the RML research mission will result in unacceptable research delays even if appropriately trained personnel could be hired at or moved to a new location. In addition, moving all or part of this program to another location would disrupt the research synergy found within the unique scientific community at RML.

The No Action alternative would result in the laboratory not being built at RML. The No Action alternative would not meet the needs of NIAID.

Resource Impacts

The Final Environmental Impact Statement (FEIS) describes potential environmental effects of the proposed project. These potential effects are documented in the FEIS in Chapter 4. The Integrated Research Facility would result in minor to negligible disruption of the physical and biological environment. Adverse environmental effects are avoided through compliance with existing regulatory requirements, application of design features, and adherence to construction requirements. Potential impacts on the economy, visual resource, historical resources, air quality, water supply, and wastewater are all within government standards (federal, state, and local), therefore; the NIH is confident that there would not be negative effects on the environment or on the citizens of Hamilton.

Summary of Impacts

The following is a summary of potential impacts resulting from the Proposed Action the NIH considered when making its decision.

Social Resources

Additional employment associated with the proposed Integrated Research Facility includes up to 200 workers at the peak of construction and up to 100 employees in late 2005/early 2006 when the facility would be opened. Based on the Ravalli County rate of 2.45 persons per household, this would add a total of 245 new residents to the county. This represents between 1.4 percent and 3 percent of all new residents projected for the County, based on estimates in the Ravalli County Economic Needs Assessment (Swanson, 2002). Addition of new homes would result in increased business for homebuilders and real estate developers. School capacity is adequate for new growth, but operating and maintenance costs would increase to accommodate the new students. No impact is expected on the ethnic or gender make-up of the population.

Traffic near the RML campus associated with construction and delivery of equipment and materials would increase over the 2-year construction period. Following construction, traffic levels would likely remain elevated due to the 100 new employees at RML (approximately 20 percent during peak hours), although large truck traffic to support RML would return to current levels.

Community Risk

Many people stated concerns with the Proposed Action throughout the comment periods. These concerns mainly related to the perceived threat the facility posed to the local community. In response to the safety concerns raised by citizens, NIH completed a risk assessment (FEIS page 4–5). The risk assessment indicated that there is essentially no risk to the community from release of infectious agents. Additionally, the safety record of BSL–4 laboratories worldwide is documented (see Appendix D of the FEIS) and shows that there has never been a community release of a biological agent from a modern maximum containment laboratory. The Proposed Action does not pose a measurable risk to the neighboring community from escaped agents.

Qualitative and quantitative risk analysis revealed that the potential risk to the community surrounding the Rocky Mountain Laboratories and specifically the Integrated Research Facility from a release of infectious agents is negligible.

Economic Resources

The Proposed Action would have direct economic impacts on both the City of Hamilton and Ravalli County throughout construction and operation. Payroll associated with construction of the Integrated Research Facility is estimated at $4.7 million. Using the current economic multiplier in the 2002 Ravalli County Needs Assessment, approximately $18.9 million in economic activity would be gained in the 2-year construction period.

Annual payroll for 100 new employees is estimated at $6.6 million. Added to the current $10.4 million annual payroll, RML would contribute $17 million annually to the local economy. RML and the proposed Integrated Research Facility meet community goals listed in the 2002 Ravalli County Economic Needs Assessment, Ravalli County Growth Policy, and the City of Hamilton Comprehensive Master Plan.

Public finance revenues would increase from income tax on the Integrated Research Facility-related construction and operations payrolls, as

well as income of spouses and older children of anticipated additional RML employees, increased number of licensed vehicles, and property tax revenues from additional new homes and property assessments.

Noise

Equipment operated during construction of the Integrated Research Facility would result in additional noise at the site. With specified noise reduction measures, the Integrated Research Facility would meet RML's 2003 noise guidelines. Recently implemented noise reduction features and reasonably foreseeable actions have and would reduce noise further.

Visual Quality

The primary visual impact of the Proposed Action would be addition of a large building (Integrated Research Facility) into an area of existing buildings on the RML campus. Existing and proposed ventilation stacks associated with the Boiler Plant would create vertical linear contrast to surrounding structures. Ventilation stacks on the Integrated Research Facility would not be visible from surrounding neighborhoods. Proposed landscaping around the Integrated Research Facility would have a positive impact on visual quality at the RML.

Historical Resources

The Proposed Action would be partially visible from the RML Historic District. The Integrated Research Facility could affect the view from the historic district, but there would be no adverse effect on the qualities inherent in the Historic District.

Air Quality

Gaseous and particulate air contaminant emissions would be generated during normal laboratory operations. Source emissions would comply with all air quality standards. Use of the incinerator to dispose of refuse generated at the facility, including that generated by the Integrated Research Facility, would increase from 2–3 days/week to 3–4 days/week. Permit limits (Montana Air Quality Permit 2991–04) on the incinerator would not be exceeded.

Water Supply and Wastewater

The estimated increase in water usage of 17,000 gallons per day represents about a 1 percent increase in the amount of water pumped by the City of Hamilton Department of Public Works (CHDPW) on a daily basis. With respect to available capacity, the Integrated Research Facility would use about 5.3 percent (12 gallons per minute of 226 gallons per minute) of system capacity. Increased demand for water caused by operation of the Integrated Research Facility would have a minor impact on the CHDPW municipal water supply system, and the system would be able to handle the increased demand.

Approximately 1,000 to 1,200 pounds of solids per day are currently handled at the CHDPW. (Lowry 2003). The Integrated Research Facility would generate an estimated 28 pounds of additional solids; representing a 2.3 to 2.8 percent increase in solids load to the CHDPW wastewater facility.

The Proposed Action would not have an impact on the solids handling capacity at the CHDPW because the planned upgrade of the solids handling capacity at the facility would accommodate current and future needs of Hamilton as well as additional solids produced by the Integrated Research Facility.

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

Pollution prevention measures are described in Chapter 2 of the FEIS and reflect standard spill prevention procedures. Additional pollution from the Integrated Research Facility is not anticipated. Air quality permit standards would be met, as would all federal, state, and local requirements to protect the environment and public health. Additional pollution prevention methods would include:

- Reducing construction waste by recycling materials wherever possible;
- Applying best management practices (BMPs) during construction to minimize soil erosion and potential airborne particulate matter; and
- Requiring that IRF activities comply with the NIH waste management policies, which emphasize source segregation, inactivation, source reduction, reuse, and recycling.

Monitoring and Enforcement Program for Mitigation Measures

During the preparation of the FEIS, several potential environmental issues associated with implementation of the Proposed Action were identified. The local community is concerned about noise during construction and operation of the Integrated Research Facility. To mitigate noise associated with these activities, measures have been included to reduce noise during construction, along with noise generated by eventual operation of the Integrated Research Facility. Noise levels associated with the current facility have been reduced through installation of noise deadening equipment. During construction of the Integrated Research Facility, hours of construction would be limited to avoid disturbing the community at night. A professional acoustics contractor would monitor noise periodically, to ensure that noise generated at RML is within the established voluntary guidelines.

RML has facilitated the formation of a group of local community representatives (the Community Liaison Group) to maintain communication with the community about operation of RML. This group would be able to bring community concerns to RML and work on resolutions.

Emergency planning was raised as a concern. RML currently has an emergency plan, which will be updated before the Integrated Research Facility becomes operational. Emergency responders in the area are confident that they would be capable of handling emergency situations.

Comments suggested that the Integrated Research Facility would be a target for terrorists. Increased security measures required of all government facilities today reduce this possibility. Rigorous security and surveillance measures will be in place to prevent unauthorized use or removal of biological material.

Redundancy of safety equipment and procedures, operational safeguards, and monitoring systems inherent in biocontainment laboratories reduce the risk of an accidental release. Theoretically, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials from a laboratory. These types of failures were addressed in the risk assessments performed. The results of the risk assessments and overall safety record of NIAID laboratories indicate that there is little or no increased risk of accidental release of infectious agents to the environment.

Transportation of agents to and from the Integrated Research Facility was a concern for some. Strict rules and regulations govern how agents are packaged, labeled, handled, tracked and transported. There is no greater risk to the surrounding community from the transport of biological material than there is anywhere else along the transport path.

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, and mitigable through adherence to guidelines outlined in Biosafety in Microbiological and Biomedical Laboratories, a joint publication of the NIH and Centers for Disease Control, as well as other standards for safe operational practices.

Conclusion

Based upon review and careful consideration, the NIH has decided to implement the Proposed Action, the construction of the Integrated Research Facility at the Rocky Mountain Laboratories in Hamilton, Montana.

The decision was based upon review and careful consideration of the impacts identified in the Final EIS; public comments received throughout the National Environmental Policy Act process, including comments on the Draft EIS and Supplemental Draft EIS and those provided during the required 30-day waiting period for the Final EIS. Other relevant factors included in the decision, such as NIAID's mandate to conduct research on agents of emerging and re-emerging infectious diseases were carefully considered. The unique scientific capabilities of the scientists at the RML, who require the selected alternative in order to perform their expanded research mission, was also a factor in the decision making process.

Dated: June 7, 2004.

Leonard Taylor, Jr.,

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

[FR Doc. 04–13642 Filed 6–16–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

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.

Identification of a Tricyclic Amino Amide (NSC–644221) Inhibitor of the Hypoxic Signaling Pathway

Giovanni Melillo (NCI).

DHHS Reference Nos. E–185–2004/0–US–01 and E–185–2004/1–US–01.

Licensing Contact: George Pipia; 301/435–5560; *pipiag@mail.nih.gov.*

This invention describes the identification of a tricyclic (1,4-dioxane) amino amide with confirmed potent activity in inhibiting HIF–1 transcriptional activity.

HIF–1 is a transcription factor and plays an important role in adaptation of cancer cells to an hypoxic environment. HIF–1 significantly increases the ability of cancer cells to survive under strenuous conditions. It contributes to the ability of cancer cells to migrate and invade surrounding tissue, and is important for the formation of new blood vessels that are essential for growth and metastasis of cancer cells. Thus HIF–1 mediates survival and spreading of cancer cells. Previous studies have shown that HIF–1 is also important in human cancers, and therefore, inhibition of HIF–1 activity is contemplated in the field as a therapy for cancer patients.

The inventors, using a cell-based high throughput screen, identified a new compound, NSC–644221, with potent inhibitory activity of the HIF–1 pathway. The compound inhibits expression of HIF–1 and reduces its accumulation in the cell. This compound also inhibits expression of endogenous genes that are under control of HIF–1, such as Vascular Endothelial Growth Factor (VEGF) that is essential for the formation of new blood vessels. The NIH inventors currently are testing the compound in angiogenesis assays and are starting preclinical studies of the compound using animal cancer models.

SH2 Domain Binding Inhibitors

Terrence R. Burke, Jr., Zhen-Dan Shi, Kyeong Lee (NCI).

U.S. Provisional Application No. 60/504,241 filed 18 Sep 2003 (DHHS Reference No. E–315–2003/0–US–01).

Licensing Contact: George Pipia; 301/435–5560; *pipiag@mail.nih.gov.*

The present invention provides for ultra-potent Grb2 SH2 domain-binding compounds, or a pharmaceutically acceptable salt thereof. The compounds of the present invention represent tetrapeptide mimetics whose conformation is constrained through macrocyclization. Low picomolar binding affinity is achieved in *in vitro* Grb2 SH2 domain binding assays. Addition of covered agent to the extracellular media of erbB–2 over-expressing breast cancer cells at low nanomolar concentrations results in effective intracellular blockade of Grb2 association with activated cytoplasmic erbB–2 tyrosine kinase. Antimitogenic effects are observed in erbB–2-dependent breast cancer cells in culture at sub-micromolar concentrations. The present invention further provides a pharmaceutical composition comprising a pharmaceutically or pharmacologically acceptable carrier and a compound of the present invention. The present invention also provides a method for inhibiting an SH2 domain from binding with a phosphoproteins comprising contacting an SH2 domain with a compound of the present invention. The present invention also provides a method of preventing or treating a disease state or condition by the use of the compound. While the invention has been described and disclosed below in connection with certain embodiments and procedures, it is not intended to limit the invention to those specific embodiments. Rather it is intended to cover all such alternative embodiments and modifications as fall within the spirit and scope of the invention.

This research is described, in part, in: Z. Shi *et al.*, ''A novel macrocyclic tetrapeptide mimetic that exhibits low-picomolar Grb2 SH2 domain-binding affinity,'' Biochem. Biophys. Res. Commun. (2003 Oct 17) 310(2):378–383, doi:10.1016/j.bbrc.2003.09.029; Z. Shi *et al.*, ''Synthesis of a 5-methylindolyl-containing macrocycle that displays ultrapotent Grb2 SH2 domain-binding affinity,'' J. Med. Chem. (2004 Feb 12) 47(4):788–791, doi:10.1021/jm030440b.

Dated: June 4, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–13641 Filed 6–16–04; 8:45 am]

BILLING CODE 4140–01–P