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 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 CUBICIN (daptomycin). CUBICIN is indicated for the treatment of complicated skin and skin structure infections caused by susceptible strains of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant strains), *Streptococcus pyogenes*, *S. agalactiae*, *S. dysgalactiae subsp. equismilis*, and *Enterococcus faecalis* (vancomycin-susceptible strains only). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CUBICIN (U.S. Patent No. 4,885,243) from Cubist Pharmaceuticals, 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 CUBICIN 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 CUBICIN is 6,444 days. Of this time, 6,177 days occurred during the testing phase of the regulatory review period, while 267 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*: January 22, 1986. The applicant claims January 18, 1986, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 22, 1986, 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(b) of the act*: December 20, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for CUBICIN (NDA 21–572) was initially submitted on December 20, 2002.

3. *The date the application was approved*: September 12, 2003. FDA has verified the applicant's claim that NDA 21–572 was approved on September 12, 2003.

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 1,347 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 August 14, 2006. 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 December 11, 2006. 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: May 17, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–9225 Filed 6–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Cooperative Research and Development Agreement (CRADA) Opportunity for Furthering the Development of a Suite of Computer Programs for Modeling and Simulating Complex Cellular Biological Processes

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), seeks to enter into a CRADA with a commercial partner to co-develop a suite of computer programs for modeling and simulating complex cellular biological processes.

The existing suite of computer programs allows biologists to develop and test quantitative models of cell biological processes. The graphical interfaces of the programs make it possible to develop realistic models of molecular interactions and cellular processes that take into account the intracellular and extracellular spatial inhomogeneity of signaling components without the user having to deal with the partial differential equations and state automata that underlie the quantitative simulation of the models. The program suite offers graphical symbols and drag-and-drop mechanisms to define molecular interactions, molecular complexes, cellular stimulus-response mechanisms, and the structure of extracellular compartments. An intuitive graphical interface can be used to inspect and interact with running simulations; for example, molecules and cells can be placed into the simulated compartments, cells can be selected for detailed analysis of their behavior and intracellular, spatially-resolved biochemistry. One part of the program suite reads the molecular interaction network data that are generated by the program based on the user defined bimolecular interactions and displays them as interaction graphs, visualizing the reaction dynamics in the modeled cellular signaling pathways.

It is anticipated that the collaboration will result in the commercialization of the software.

DATES: NIAID will consider all capability statements received within 45 days of the date of publication of this notice. Capability statements received thereafter may be considered if a

suitable CRADA collaborator has not been selected.

FOR FURTHER INFORMATION CONTACT: Queries and capability statements should be addressed to William C. Ronnenberg, JD, M.I.P., Office of Technology Development, National Institute of Allergy and Infectious Diseases, 6610 Rockledge Drive, Room 4071, MSC 6606, Bethesda, MD 20892–6606 (Zip Code for Courier: 20817), telephone 301–451–3522, fax: 301–402–7123, e-mail: *wronnenberg@niaid.nih.gov.*

SUPPLEMENTARY INFORMATION: With the increased availability of detailed proteomic data, the main obstacle to developing realistic software-based simulation models of cellular signaling processes is the technical difficulty of transforming complex biological models into quantitative simulations. Biological models typically describe cellular signaling processes in terms of bimolecular interactions or the interaction between specific sites on two proteins. These bimolecular interactions can be integrated by available software into diagrammatic representations of signaling pathways. However, these descriptions are generally qualitative and are not useful for a quantitative understanding of the underlying biological systems. For quantitative representations of biological models, the current approach is to ask theorists (mathematicians, physicists, etc.) to transform these qualitative models into sets of equations or automata rules that roughly reflect the properties of the original model. The resulting descriptions of complex biological models are frequently inadequate because the theorist involved lacks an understanding of biological details or the resulting mathematical descriptions are over-simplified.

The goals of the proposed CRADA are to integrate an existing software program for the simulation of multi-scale, cellular, biological models with protein database interfaces and to improve the software's graphical user interface. NIAID has developed, in part, software that simulates reaction networks of all possible molecular interactions in biological systems based on user inputs. The current development stage of the software combines several unique features, such as a graphical interface for the definition and simulation of cell biological models spanning the scale from bi-molecular interactions to the behavior of cell populations. Its internal algorithms for the integration of the partial differential equations governing the spatio-temporal behavior of the simulated biological system use state-of-the-art approaches to deal with very large reaction networks and the stiffness of the equations.

Simulations created with the software take into account the differential behavior of cytosolic and membrane-bound complexes as well as transmembrane signaling events and generates the equivalent of a set of partial differential equations describing the spatio-temporal dynamics of the system. The graphical user interface of the software allows the user to define bi-molecular interactions, enzymatic transformations, (initial) spatial distribution of the components of cellular biochemistry and the location of cells within extracellular spatial compartments. Based on the initial distribution of molecules and cells defined by the user the software then simulates the behavior of the system providing a range of different graphical and tabular representations of the system's evolving state. At any time during the simulations, the user can add components (cells, molecules) and query the detailed biochemical state of cells (localized concentrations of signaling components) and investigate how these correlate with the cells' behavior.

The capability statement must address, with specificity, each of the following selection criteria:

(1) A demonstration of expertise and experience in the areas of design and coding of biological software with an extensive GUI component, as well as the development of supporting documentation;

(2) A demonstration of and a willingness to commit reasonable and adequate resources (including facilities, equipment, and personnel) the development of this technology;

(3) A demonstration of the expertise and ability to commercially develop, produce, sell, and provide user support for similar technologies; and

(4) Ability to provide adequate and sustained funding for CRADA activities.

Dated: June 2, 2006.

Michael R. Mowatt,

Director, Office of Technology Development, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

[FR Doc. E6–9301 Filed 6–13–06; 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, 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.

Generation of Regulatory T Cells for Immunotherapy

Description of Technology: Abnormalities in immunoregulation are responsible for a wide variety of disorders such as autoimmune disease, chronic inflammatory diseases, and allergic diseases. These diseases include systemic lupus erythematosus, rheumatoid arthritis, type I diabetes mellitus, inflammatory bowel disease, multiple sclerosis, Crohn's disease and asthma. The defining event for induction of an immune-mediated disorder is the loss of T cell tolerance to self-antigens, which is provided by regulatory T cells. Traditional methods for treating immune-mediated disorders involve the use of steroids or other immunosuppressive drugs, which have significant undesirable side effects.

This invention provides methods for generating regulatory T cells by culturing CD4+CD25 − T cells with autologous antigen-presenting cells (APCs) in the presence of the Th2 cytokines interleukin-4 (IL-4) and/or interleukin-13 (IL-13). Immunotherapy via this mechanism is anticipated to have a large number of potential therapeutic applications. Methods are also provided for treatment of