

not oblige NOAA to award any specific project or to obligate any available funds.

National Environmental Policy Act (NEPA): NOAA must analyze the potential environmental impacts, as required by the National Environmental Policy Act (NEPA), for applicant projects or proposals which are seeking NOAA federal funding opportunities. Detailed information on NOAA compliance with NEPA can be found at the following NOAA NEPA Web site: <http://www.nepa.noaa.gov/>, including our NOAA Administrative Order 216-6 for NEPA, http://www.nepa.noaa.gov/NAO216_6_TOC.pdf, and the Council on Environmental Quality implementation regulations, http://ceq.eh.doe.gov/nepa/regs/ceq/toc_ceq.htm. Consequently, as part of an applicant's package, and under their description of their program activities, applicants are required to provide detailed information on the activities to be conducted, locations, sites, species and habitat to be affected, possible construction activities, and any environmental concerns that may exist (e.g., the use and disposal of hazardous or toxic chemicals, introduction of non-indigenous species, impacts to endangered and threatened species, aquaculture projects, and impacts to coral reef systems). In addition to providing specific information that will serve as the basis for any required impact analyses, applicants may also be requested to assist NOAA in drafting of an environmental assessment, if NOAA determines an assessment is required. Applicants will also be required to cooperate with NOAA in identifying feasible measures to reduce or avoid any identified adverse environmental impacts of their proposal. The failure to do so shall be grounds for not selecting an application. In some cases if additional information is required after an application is selected, funds can be withheld by the Grants Officer under a special award condition requiring the recipient to submit additional environmental compliance information sufficient to enable NOAA to make an assessment on any impacts that a project may have on the environment.

The Department Of Commerce Pre-Award Notification Requirements For Grants And Cooperative Agreements: The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of February 11, 2008 (73 FR 7696), are applicable to this solicitation.

Paperwork Reduction Act: This document contains collection-of-information requirements subject to the

Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, and SF-LLL and CD-346 has been approved by the Office of Management and Budget (OMB) under the respective control numbers 0348-0043, 0348-0044, 0348-0040, 0348-0046, and 0605-0001.

Notwithstanding any other provision of law, no person is required to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

Executive Order 12866: This notice has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 13132 (Federalism): It has been determined that this notice does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

Administrative Procedure Act/Regulatory Flexibility Act: Prior notice and an opportunity for public comment are not required by the Administrative Procedure Act or any other law for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements for the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Charles S. Baker,

Deputy Assistant Administrator for Satellite and Information Services.

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2008-0060]

Grant of Interim Extension of the Term of U.S. Patent No. 4,971,802; Mifamurtide

AGENCY: United States Patent and Trademark Office.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. 156(d)(5) for a second one-year interim extension of the term of U.S. Patent No. 4,971,802.

FOR FURTHER INFORMATION CONTACT: Raul Tamayo by telephone at (571) 272-7728; by mail marked to his attention and

addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to his attention at (571) 273-7728, or by e-mail to Raul.Tamayo@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On October 10, 2008, IDM Pharma, agent/licensee of patent owner Novartis, timely filed an application under 35 U.S.C. 156(d)(5) for a second interim extension of the term of U.S. Patent No. 4,971,802. Claims of the patent cover the product Mifamurtide having the active ingredient muramyl tripeptide phosphatidyl ethanolamine. The application indicates, and the Food and Drug Administration has confirmed, that a New Drug Application for the human drug product Mifamurtide has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (November 20, 2008), interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A second interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,971,802 is granted for a period of one year from the extended expiration date of the patent, i.e., until November 20, 2009.

Dated: December 18, 2008.

John J. Doll,

Acting Deputy Under Secretary of Commerce for Intellectual Property and Acting Deputy Director of the United States Patent and Trademark Office.

[FR Doc. E8-30781 Filed 12-24-08; 8:45 am]

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