

Technology, and Finance, Office of Information and Resource Management, Attention: Naomi Cook (0937-0191), Room 531-H, 200 Independence Avenue, SW., Washington, DC 20201.

Dated: September 21, 2004.

**Robert E. Polson,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 04-21888 Filed 9-29-04; 8:45 am]

**BILLING CODE 4168-17-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: OS-0990-0115]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Office of the Secretary.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#1 *Type of Information Collection Request:* Extension of a Currently Approved Collection;

*Title of Information Collection:* HHS Acquisition Regulation—Solicitation and Contracts;

*Form/OMB No.:* OS-0990-0115;

*Use:* Information is needed to evaluate feasibility of contractor(s) scientific or technical approach, management plan, and cost to accomplish the program or services required by the government.

*Frequency:* Recordkeeping, reporting;

*Affected Public:* State, local, or tribal governments and not-for-profit institutions;

*Annual Number of Respondents:* 5,357;

*Total Annual Responses:* 5,357;

*Average Burden Per Response:* 1 hour;

*Total Annual Hours:* 883,905;

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at <http://www.hhs.gov/oirm/infocollect/pending/> or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to [naomi.cook@hhs.gov](mailto:naomi.cook@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer at the following address: OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, Attention: (OMB #0990-0115), New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 21, 2004.

**Robert E. Polson,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 04-21889 Filed 9-29-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Findings of Scientific Misconduct

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the Office of Research Integrity (ORI) and the Acting Assistant Secretary for Health have taken final action in the following case:

*Charles N. Rudick, Northwestern University:* Based on the report of an investigation conducted by Northwestern University (NU Report) and additional analysis conducted by ORI in its oversight review, PHS found that Charles N. Rudick, Graduate Student, Department of Neurobiology and Physiology at NU (Respondent), engaged in scientific misconduct in research supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant R29 NS37324, "Estrogen-induced hippocampal seizure susceptibility," and National Institute of General Medical Sciences (NIGMS), NIH, grant T32 GM08061, "Cellular and Molecular Basis of Disease Training Program."

Specifically, PHS found that Mr. Rudick falsified illustrations in Photoshop pertaining to unpublished

traces of electrophysiological recordings of inhibitory postsynaptic currents.

Mr. Rudick has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of three (3) years, beginning on September 14, 2004:

(1) To exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That any institution which submits an application for PHS support for a research project on which the Respondent's participation is proposed or which uses the Respondent in any capacity on PHS supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution. Respondent agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution. Respondent agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to and accepted by ORI.

**FOR FURTHER INFORMATION CONTACT:** Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443-5330.

**Chris B. Pascal,**

*Director, Office of Research Integrity.*

[FR Doc. 04-21920 Filed 9-29-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003E-0260]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; AMEVIVE

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for AMEVIVE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an

application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit written or electronic comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product AMEVIVE (alefacept). AMEVIVE is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. Subsequent to this approval, the Patent

and Trademark Office received a patent term restoration application for AMEVIVE (U.S. Patent No. 5,547,853) from Biogen, 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 November 18, 2003, FDA advised the Patent and Trademark Office that this human biologic product had undergone a regulatory review period and that the approval of AMEVIVE 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 AMEVIVE is 2,104 days. Of this time, 1,618 days occurred during the testing phase of the regulatory review period, while 486 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 (21 U.S.C. 355(i)) became effective (21 U.S.C. 355(i)):* April 29, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 29, 1997.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* October 2, 2001. FDA has verified the applicant's claim that the biological license application (BLA) for Amevive (BLA 12536) was initially submitted on October 2, 2001.

3. *The date the application was approved:* January 30, 2003. FDA has verified the applicant's claim that BLA 12536 was approved on January 30, 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 1,259 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 comments and ask for a redetermination by November 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 March 29, 2005. 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: August 30, 2004.

**Jane A. Axelrad,**

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

[FR Doc. 04-21874 Filed 9-29-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 2004M-0147, 2004M-0145, 2004M-0207, 2004M-0253, 2004M-0165, 2004M-0200, 2004M-0199, 2004M-0256, 2004M-0248, 2004M-0249, 2004M-0250, 2004M-0260, and 2004M-0259]

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Think Nguyen, Center for Devices and