

Form Number: CMS-R-142 (OMB#: 0938-0667); Frequency: Daily; Affected Public: Individuals or households, Private Sector; Number of Respondents: 6,149; Total Annual Responses: 6,149; Total Annual Hours: 1. (For policy questions regarding this collection contact Renate Rockwell at 410-786-1326. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on May 24, 2010.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: OIRA_submission@omb.eop.gov.

Dated: April 15, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-9501 Filed 4-22-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request Web Based Training for Pain Management Providers

Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** in Vol. 75, No. 25, pages 6208-6209 on Monday, February 8, 2010 and allowed 60 days for public comment. No public comments were received on the planned study or any of the specific topics outlined in the 60-day notice. Five comments were received requesting information on the educational program rather than the study. Responses to these requests were sent to the interested parties. The purpose of this notice is to allow an additional 30 days for public comment. 5 CFR 1320.5 (General requirements) Reporting and Recordkeeping Requirements: Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Proposed Collection

Title: Web Based Training for Pain Management Providers.

Type of Information Collection Request: New.

Need and Use of Information Collection: This research will evaluate the effectiveness of the Web Based

Training for Pain Management Providers, via the Web site PainAndAddictionTreatment.com, to positively impact the knowledge, attitudes, intended behaviors and clinical skills of health care providers in the US who treat pain. The Web Based Training for Pain Management Providers is a new program developed with funding from the National Institute on Drug Abuse. The primary goal is to assess the impact of the training program on knowledge, attitude, intended behavior, and clinical skills. A secondary goal is to assess learner satisfaction with the program. If the program is a success, there will be a new, proven resource available to health care providers to improve their ability to treat pain and addiction co-occurring in the provider's patients. In order to evaluate the effectiveness of the program, information will be collected from health care providers before exposure to the web based materials (pre-test), after exposure to the web based materials (post-test), and 4-6 weeks after the program has been completed (follow-up).

Frequency of Response: On occasion.

Affected Public: Volunteer health care providers who treat patients with pain.

Type of Respondents: Physicians, nurse practitioners, and physician assistants.

The annual reporting burden is as follows:

Estimated Number of Respondents: 80.

Estimated Number of Responses per Respondent: 3.

Average Burden Hours per Response: 0.75.

Estimated Total Annual Burden Hours Requested: 180.

The annualized cost to respondents is estimated at: \$11,925. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated Number of responses per respondent	Average burden hours per response	Estimated annual burden hours requested
Physicians	60	3	0.75	135
Other primary care providers (e.g., nurse practitioners, physician assistants)	20	3	0.75	45

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper

performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the

validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who

are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Scudder Quandra, Project Officer, NIH/NIDA/CCTN, Room 3105, MSC 9557, 6001 Executive Boulevard, Bethesda, MD 20892-9557 or e-mail your request, including your address to *scudderq@nida.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 15, 2010.

Mary Affeldt,

*Executive Officer, (OM Director, NIDA),
National Institutes of Health.*

[FR Doc. 2010-9374 Filed 4-22-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2009-E-0172 and FDA-2009-E-0174]

Determination of Regulatory Review Period for Purposes of Patent Extension; VIMPAT—NDA 22-253

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VIMPAT based on new drug application (NDA) 22-253 for VIMPAT TABLETS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extensions of patents which claim the human drug product, VIMPAT. The regulatory review period determination for VIMPAT Injection is publishing in this issue of the **Federal Register**.

ADDRESSES: Submit written 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes 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, VIMPAT (lacosamide). VIMPAT tablets are indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for VIMPAT (U.S. Patent Nos. 5,654,301 and RE38,551) from Research Corporation Technologies, Inc., and the Patent and Trademark Office requested

FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VIMPAT represented the first permitted commercial marketing or use of the product. 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 VIMPAT is 3,452 days. Of this time, 3,055 days occurred during the testing phase of the regulatory review period, while 397 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 19, 1999. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 19, 1999.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 28, 2007. FDA has verified the applicant's claim that the new drug application (NDA 22-253) for VIMPAT tablets was submitted on September 28, 2007.

3. *The date the application was approved:* October 28, 2008. FDA has verified the applicant's claim that NDA 22-253 was approved on October 28, 2008.

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 1,827 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 June 22, 2010. 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 October 20, 2010. 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.