

diabetic peripheral neuropathy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LYRICA (NDA 21-446) (U.S. Patent No. 6,197,819) from Warner-Lambert Company LLC, 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 LYRICA (NDA 21-446) 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 LYRICA (NDA 21-446) is 3,279 days. Of this time, 2,852 days occurred during the testing phase of the regulatory review period, while 427 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 10, 1996. The applicant claims August 24, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 10, 1996, which was 30 days after FDA receipt of the initial IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* October 31, 2003. The applicant claims October 30, 2003, as the date the new drug application (NDA) for LYRICA (NDA 21-446) was initially submitted. However, FDA records indicate that NDA 21-446 was initially submitted on October 31, 2003.

3. *The date the application was approved:* December 30, 2004. FDA has verified the applicant's claim that NDA 21-446 was approved on December 30, 2004.

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 299 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 November 27, 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 March 26, 2007. 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: September 15, 2006.

Jane A. Axelrad,

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

[FR Doc. E6-15908 Filed 9-26-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2006-0054]

Notice of Meeting of National Infrastructure Advisory Council (NIAC)

AGENCY: Directorate for Preparedness, DHS.

ACTION: Notice of meeting.

SUMMARY: The National Infrastructure Advisory Council (NIAC) will meet in open session.

DATES: Tuesday, October 10, 2006, from 1:30 p.m. to 4:30 p.m.

ADDRESSES: National Press Club, 529 14th Street, NW., Washington, DC 20045. You may submit comments, identified by DHS-2006-0054, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- E-mail: william.corcoran@associates.dhs.gov.

When submitting comments electronically, please include by DHS-2006-0054, in the subject line of the message.

- Mail: Jenny Menna, Department of Homeland Security, Directorate for

Preparedness, Washington, DC 20528. To ensure proper handling, please reference by DHS-2006-0054, on your correspondence. This mailing address may be used for paper, disk or CD-ROM submissions.

- Hand Delivery/Courier: Jenny Menna, Department of Homeland Security, Directorate for Preparedness, Washington, DC 20528. Contact Telephone Number 703-235-5316.

Instructions: All submissions received must include the words "Department of Homeland Security" and DHS-2006-0054, the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Jenny Menna, NIAC Designated Federal Officer, Department of Homeland Security, Washington, DC 20528; telephone 703-235-5316.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.1 *et seq.*). At this meeting, the NIAC will be briefed on the status of several Working Group activities in which the Council is currently engaged.

This meeting is open to the public on a first-come, first-served basis. Please note that the meeting may close early if all business is finished.

A tentative agenda for the meeting is set forth below, but may be updated. Please consult the NIAC Web site, <http://www.dhs.gov/niac>, for the most current agenda.

Information on Services for Individuals with Disabilities: For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, telephone the Designated Federal Officer as soon as possible.

Dated: September 18, 2006.

Jenny Menna,

Designated Federal Officer for the NIAC.

Draft Agenda of October 10, 2006 Meeting

- I. Opening of Meeting: *Jenny Menna*, Designated Federal Officer, NIAC, Department of Homeland Security.
- II. Roll Call of Members: *Jenny Menna*.
- III. Opening Remarks and Introductions: NIAC Chairman, *Erle A. Nye*, Chairman Emeritus, TXU Corp, NIAC Vice Chairman, *John T. Chambers*, President and CEO, Cisco Systems, Inc, *Michael*

- Chertoff*, Secretary, Department of Homeland Security (DHS) (*Invited*), *Frances Fragos Townsend*, Assistant to the President for Homeland Security and Counterterrorism (*Invited*).
- IV. Approval of July Minutes: NIAC Chairman, *Erle A. Nye*.
- V. Final Reports and Deliberations: NIAC Chairman, *Erle A. Nye* Presiding.
- A. The Prioritization of Critical Infrastructures for a Pandemic Outbreak in the United States: *Chief Rebecca F. Denlinger*, Fire Chief, Cobb County, Georgia Fire and Emergency Services, NIAC Member, *Martha H. Marsh*, Chairman and CEO, Stanford Hospital and Clinics, NIAC Member and *Bruce Rohde*, Chairman and CEO Emeritus, ConAgra Foods, Inc.
- B. Deliberation and Approval of Recommendations of Final Report: *NIAC Members*.
- VI. Status Report on Current Working Group Initiatives: NIAC Chairman, *Erle A. Nye* Presiding.
- A. Convergence of Physical and Cyber Technologies and Related Security Management Challenges: *George Conrades*, Executive Chairman, Akamai Technologies, NIAC Member, *Margaret Grayson*, President, AEP Government Solutions Group, NIAC Member, and *Gregory A. Peters*, Former President and CEO, Internap Network Services Corporation, NIAC Member.
- VII. New Business: NIAC Chairman, *Erle A. Nye*, NIAC Members TBD.
- A. Discussion of Potential New Working Group Topics: *NIAC Members*.
- B. Recommendations Follow-up: *Nancy Wong*, Designated Federal Officer, DHS.
- VIII. Adjournment: NIAC Chairman, *Erle A. Nye*.

[FR Doc. E6-15864 Filed 9-26-06; 8:45 am]

BILLING CODE 4410-10-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Revision of a Currently Approved Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Application for T Nonimmigrant Status; Application for Immediate Family Member of T-1

Recipient; and Declaration of Law Enforcement Officer for Victim of Trafficking in Persons; Form I-914 and Supplements A and B; OMB Control No. 1615-0099.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until November 27, 2006.

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 Department of Homeland Security (DHS), USCIS, Director, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at rfs.regs@dhs.gov. When submitting comments by e-mail please make sure to add OMB Control Number 1615-0099 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

- (1) *Type of Information Collection:* Revision of an existing information collection.
- (2) *Title of the Form/Collection:* Application for T Nonimmigrant Status; Application for Immediate Family Member of T-1 Recipient; and Declaration of Law Enforcement Officer for Victim of Trafficking in Persons.

Overview of this information collection:

- (1) *Type of Information Collection:* Revision of an existing information collection.
- (2) *Title of the Form/Collection:* Application for T Nonimmigrant Status; Application for Immediate Family Member of T-1 Recipient; and Declaration of Law Enforcement Officer for Victim of Trafficking in Persons.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-914 and Supplements A and B. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and households. This application permits victims of severe forms of trafficking and their immediate family members to demonstrate that they qualify for temporary nonimmigrant status pursuant to the Victims of Trafficking and Violence Protection Act of 2000 (VTVPA), and to receive temporary immigration benefits.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Form I-914 (500 responses at 2.25 hours per response); Supplement A (500 responses at 1 hour per response); Supplement B (200 responses at .5 hours per response);

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,725 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the USCIS Web site at: <http://uscis.gov/graphics/formsfee/forms/prs/index.htm>.

If additional information is required contact: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, 3rd Floor, Washington, DC 20529, (202) 272-8377.

Dated: September 22, 2006.

Stephen Tarragon,

Acting Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. E6-15785 Filed 9-26-06; 8:45 am]

BILLING CODE 4410-10-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1018-0014; Special Use Permit Applications for National Wildlife Refuges in Alaska

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. The ICR, which is