The information collection is needed: (1) To ensure compliance with title IV–E foster care eligibility requirements; (2) to monitor State plan requirements under titles IV–B and IV–E of the Act, as required by Federal statute; and (3) to enforce the title IV–E anti-discrimination requirements through State corrective action plans. The resultant information will allow ACF to determine if States are in compliance with State plan requirements and are achieving desired outcomes for children and families, help ensure that claims by States for title IV–E funds are made on behalf of title IV–E eligible children, and require States to revise applicable statutes, rules, policies and procedures, and provide proper training to staff, through the development and implementation of corrective action plans. These reviews not only address compliance with eligibility requirements but also assist States in enhancing the capacities to serve children and families. In computing the number of burden hours for this information collection, ACF based the annual burden estimates on ACF's and States' experiences in conducting reviews and developing program improvement plans.

Respondents: State Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 1356.7 (i) Program Improvement Plan (FCER)	7	1	90	630
45 CFR 1366.33 (b) Statewide Assessment (CFSR)	13	1	240	3,120
45 CFR 1355.33 (c) On-site Review (CFSR)	13	1	1,170	15,210
45 CFR 1355.35 (a) Program Improvement Plan (CFSR)	13	1	240	3,120
45 CFR 1355.38 (b) and (c) Corrective Action Plan (Anti-discrimination enforcement)	1	1	780	780

Estimated Total Annual Burden Hours: 22,860.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Office for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: September 20, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–8272 Filed 9–26–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0006]

Determination of Regulatory Review Period for Purposes of Patent Extension; LYRICA (New Drug Application 21–446)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LYRICA (new drug application (NDA) 21–446) 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 drug product.

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.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 human drug product 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 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 LYRICA (NDA 21–446) (pregabalin). LYRICA (NDA 21–446) is indicated for management of neuropathic pain associated with

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*