

pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12350 Filed 5–28–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0035]

Determination of Regulatory Review Period for Purposes of Patent Extension; XARELTO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XARELTO 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 electronic comments to <http://www.regulations.gov>. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 has approved for marketing the human drug product XARELTO (rivaroxaban). XARELTO is indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism in patients undergoing knee or hip replacement surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XARELTO (U.S. Patent No. 7,157,456) from Bayer Pharma Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 9, 2012, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of XARELTO 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 XARELTO is 3,291 days. Of this time, 2,222 days occurred during the testing phase of the regulatory review period, while 1,069 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* June 29, 2002. The applicant claims June 30, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 29, 2002, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 28, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for XARELTO (NDA 22–406) was submitted on July 28, 2008.

3. *The date the application was approved:* July 1, 2011. FDA has verified the applicant's claim that NDA 22–406 was approved on July 1, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the 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 1,354 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**) either electronic or written comments and ask for a redetermination by July 28, 2014. 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 November 25, 2014. 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this

document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA-2013-S-0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Generic Clearance to Support the Safe to Sleep Campaign at the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 30, 2013, pages 79472-79473 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Child Health and Human Development, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

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: NIH Desk Officer.

Comment 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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496-1877 or Email your request, including your address to glavins@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Generic Clearance to Support the Safe to Sleep Campaign at the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD), 0925-NEW, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for a new generic clearance that would be used for submissions specific to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Safe to Sleep (STS) public education campaign. Submissions for the STS campaign will be used to assess the understanding and reach of STS campaign materials and messages, and to monitor and improve campaign activities such as training workshops and overall implementation. The purpose of this information collection is to monitor and modify campaign activities, to plan future campaign activities, to develop messages and materials, and to develop distribution and outreach strategies that are effective at communicating their message to bring about the intended response, awareness, and/or behavioral change for the target audiences. This generic clearance will enable the NICHD to: (1) More efficiently assess the implementation of campaign activities; (2) better understand the target audiences' knowledge, attitudes, and beliefs toward STS messages and materials; (3) better understand how the campaign activities have influenced the target audiences' behaviors and practices; and (4) monitor

and improve activities such as trainings, and material/message development. Having a way to gather feedback on the STS campaign activities is critical to assessing the reach and effect of campaign efforts. Data collected for the campaign can inform where future STS campaign resources can produce the most meaningful results.

Data collected for the STS campaign generic clearance will be used by a number of audiences, including STS campaign staff, NICHD leadership, STS campaign collaborators, Federal Sudden and Unexpected Infant Deaths (SUID)/ Sudden Infant Death Syndrome (SIDS) Workgroup members, SUID/SIDS stakeholders, clinical and maternal/child health professionals, parents and caretakers, and the general public. These audiences may use the information collections to: (1) Develop new campaign messages, materials, and/or training curricula; (2) monitor and improve campaign activities; (3) make decisions about campaign activities; (4) inform current campaign activities; and (5) inform and/or change practices and behaviors of program participants.

Examples of the types of information collections that could be included under this generic clearance include: *Focus groups and in-depth interviews* with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages; and *Surveys* with parents/caregivers and/or health professionals to: (1) Assess the usefulness of the new STS campaign materials, including print and on-line materials and a video, (2) track outreach experiences of program participants, (3) assess training participants' changes in knowledge related to safe infant sleep behavior and implementation of outreach methods taught, and (4) assess program participants' resource needs.

The sub-studies for this generic will be small scale, designed to obtain results frequently and quickly to guide campaign development and implementation, inform campaign direction, and be used internally for campaign management purposes. NICHD's current scope and capacity for STS generic sub-studies is non-existent and this request would fill this gap.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 3,000.

Estimated Annualized Burden Hours