505(b) of the act: June 15, 2004. The applicant claims May 14, 2004, as the date the biologics license application (BLA) for KEPIVANCE (BLA 125103) was initially submitted. However, FDA records indicate that the final reviewable unit of BLA 125103 was submitted on June 15, 2004.

3. *The date the application was approved*: December 15, 2004. FDA has verified the applicant's claim that BLA 125103 was approved on December 15, 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 1,417 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 1, 2007. 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 1, 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: February 26, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–6053 Filed 3–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0256]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RANEXA 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–7), 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 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 RANEXA (ranolazine). RANEXA is indicated for treatment of chronic angina. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for RANEXA (U.S. Patent No. 4,567,264) from Roche Palo Alto, L.L.C., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 5, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of RANEXA 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 RANEXA is 6,770 days. Of this time, 5,645 days occurred during the testing phase of the regulatory review period, while 1,125 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: July 18, 1987. The applicant claims July 10, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 18, 1987, 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 act*: December 30, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for RANEXA (NDA 21–526) was initially submitted on December 30, 2002.

3. *The date the application was approved*: January 27, 2006. FDA has verified the applicant's claim that NDA 21–526 was approved on January 27, 2006.

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 5 years 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 1, 2007. 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 1, 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: March 12, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–6061 Filed 3–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The 10th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following conference: 10th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the Drug, Device, and Biologics industries with an opportunity to interact with FDA reviewers and compliance officers from the Centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive questions and answers, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 11 and 12, 2007, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949–608–4413, FAX: 949–608–4417, or OCRA, Attention to Detail (ATD), 5319 University Dr., suite 641, Irvine, CA 92612, 949–387–9046, FAX: 949–387–9047, Web site: *www.ocra-dg.org*.

Registration and Meeting Information: See OCRA Web site, *www.ocra-dg.org*. Contact ATD at 949–387–9046.

Before May 11, 2007, registrations fees are as follows: $575.00 for members, $625.00 for non-members and $400.00 for FDA/Govt/Students. After May 11, 2007, $625.00 for members, $725.00 for non-members, and $400.00 for FDA/Govt/Students.

OCRA student rate applies to those individuals enrolled in a Regulatory or Quality related academic program at an accredited institution. Proof of enrollment required.

The registration fee will cover actual expenses including refreshments, lunch, materials, parking and speaker expenses. If you need special accommodations due to a disability, please contact Linda Hartley at least 10 days in advance.

Dated: March 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6052 Filed 3–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0114]

Electronic Distribution of Prescribing Information for Prescription Drug Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to solicit views and information from interested parties concerning the concept of electronic distribution of FDA-approved prescribing information currently contained in the package insert (or PIs) for human prescription drug and biological products. In particular, FDA is seeking views and information on the feasibility of establishing a modern and efficient process for industry to electronically distribute prescribing information to dispensers. We are seeking input on a number of questions regarding the current use of package inserts and those logistical issues associated with electronic distribution of such prescribing information.

DATES: *Public Hearing*: The public hearing will be held on April 27, 2007, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the public hearing may be extended later or may end early. If you need special accommodations due to a disability, please contact Erik Mettler (see **FOR FURTHER INFORMATION CONTACT**) by April 20, 2007.

Registration: Seating at the public hearing is limited. Registration is free and will be on a first-come, first-serve basis. Persons interested in attending the public hearing should register by close of business on April 20, 2007.

Notice of Oral Presentation: Persons interested in presenting responses to the questions should submit a notice of oral presentation by close of business on April 17, 2007. See section I of this document for information on how to participate in the public hearing.

Comments: Submit written or electronic comments by June 22, 2007.

ADDRESSES: *Public Hearing*: The public hearing will be held at 5600 Fishers Lane, third Fl., conference rooms D & E, Rockville, MD 20857.

Registration: Submit written registration to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic registration to *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*.

Notice of Oral Presentation and Comments: Submit written notices of oral presentation and comments to the Division of Dockets Management (see previous paragraph). Submit electronic notices of oral presentation and comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm*. Identify all submissions to the docket with the docket number found in