requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KINERET is 4,101 days. Of this time, 3,413 days occurred during the testing phase of the regulatory review period, while 688 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 (21 U.S.C. 355(i)) became effective*: August 25, 1990. The applicant claims August 23, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 25, 1990, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: December 28, 1999. The applicant claims December 27, 1999, as the date the product license application (BLA) for KINERET (BLA 103950) was initially submitted. However, FDA records indicate that BLA 103950 was submitted on December 28, 1999.

3. *The date the application was approved*: November 14, 2001. FDA has verified the applicant's claim that BLA 103950 was approved on November 14, 2001.

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 1,825 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 29, 2004. 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 28, 2005. 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: August 30, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–21675 Filed 9–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001E–0032]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VISUDYNE 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 that 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: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

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 VISUDYNE (verteporfin). VISUDYNE is indicated for the treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VISUDYNE (U.S. Patent No. 5,095,030) from University of British Columbia, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 2, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VISUDYNE 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 VISUDYNE is 3,194 days. Of this time, 2,953 days occurred during the testing phase of the regulatory review period, while 241 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 17, 1991. The applicant claims June 21, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the

IND effective date was July 17, 1991, 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*: August 16, 1999. The applicant claims August 24, 1999, as the date the new drug application (NDA) for VISUDYNE (NDA 21–119) was initially submitted. However, FDA records indicate that NDA 21–119 was submitted on August 16, 1999.

3. *The date the application was approved*: April 12, 2000. FDA has verified the applicant's claim that NDA 21–119 was approved on April 12, 2000.

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 November 29, 2004. 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 28, 2005. 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: August 30, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–21678 Filed 9–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0423]

Second Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee and Modernization Act of 2002 Provisions; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Second Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The topic of discussion is the agency's progress in implementing the various MDUFMA provisions, including the guidances FDA has issued on the new law.

DATES: The public meeting will be held on November 18, 2004, from 9 a.m. to 5 p.m. Registration is required by Friday, October 22, 2004. All individuals wishing to make a presentation or to speak on an issue should indicate their intent and the topic to be addressed and provide an abstract of the topic to be presented by October 22, 2004. Time for presentations will be limited to 10 minutes.

ADDRESSES: The public meeting will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Submit written requests to make an oral presentation to Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 121, FAX: 301–443–8818, e-mail: *cxg@cdrh.fda.gov*. Include your name, title, firm name, address, telephone, and fax number with your request. All requests and presentation materials should include the docket number found in brackets in the heading of this document. Submit all request for suggestions and recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 121, FAX: 301–443–8818, e-mail: *cxg@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act to include several new significant provisions. MDUFMA authorizes the following provisions: (1) User fees for certain premarket applications, (2) establishment of good manufacturing practice (GMP) inspections by FDA-accredited persons (third-parties), and (3) new requirements for reprocessed single-use devices. In addition, the new law contains several provisions that, while narrower in scope than the previously mentioned provisions, are significant changes to the device law. These include a modular review program for premarket approval applications (PMAs), electronic labeling for certain prescription devices, several provisions concerning devices for pediatric use, and a new labeling requirement that requires the manufacturer's name to appear on the device itself, with certain exceptions.

The agency has been working to implement the new law since its passage in October 2002. During this time, FDA has accomplished the following significant milestones: (1) Established a user fee program with payment, billing, and appeals procedures; (2) published accreditation criteria for persons conducting third-party inspections and accredited 15 such persons; (3) identified certain reprocessed single-use devices that will be subject to additional marketing requirements; and (4) published guidances related to the PMA, premarket notification (510(k)), and biologics license application (BLA) programs, bundling multiple devices in a single application, and premarket review of pediatric devices. The agency is drafting additional documents to be issued in the near future.

II. Agenda

On November 18, 2004, FDA is providing the opportunity for all interested persons to provide information and share their views on the implementation of MDUFMA. The following topics will be discussed:

- User Fees Process—This panel will consider the small business determination and the user fee payment processes.

Premarket Review Performance Goals—This panel will discuss the agency's progress in meeting the PMA, 510(k), and BLA review performance goals.

- Qualitative Performance Goals (e.g., Modular PMA and GMP and