application for PHAKIC INTRAOCULAR LENSES (U.S. Patent No. 5,192,319) from Ophtec USA, Inc., subsidiary of Ophtec B.V., 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 medical device had undergone a regulatory review period and that the approval of PHAKIC INTRAOCULAR LENSES 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 PHAKIC INTRAOCULAR LENSES is 2,545 days. Of this time, 2,107 days occurred during the testing phase of the regulatory review period, while 438 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: September 24, 1997. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective September 24, 1997.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: July 1, 2003. FDA has verified the applicant's claim that the premarket approval application (PMA) for PHAKIC INTRAOCULAR LENSES (PMA P030028) was initially submitted July 1, 2003.

3. *The date the application was approved*: September 10, 2004. FDA has verified the applicant's claim that PMA P030028 was approved on September 10, 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 1,484 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 July 31, 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 November 28, 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: May 7, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–10631 Filed 5–31–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0234]

Determination of Regulatory Review Period for Purposes of Patent Extension; GEM 21S GROWTH–FACTOR ENHANCED MATRIX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GEM 21S GROWTH–FACTOR ENHANCED MATRIX 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 medical device.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA approved for marketing the medical device, GEM 21S GROWTH–FACTOR ENHANCED MATRIX. GEM 21S GROWTH–FACTOR ENHANCED MATRIX is indicated to treat the following periodontally related defects: (1) Intrabony periodontal defects, (2) furcation periodontal defects, and (3) gingival recession associated with periodontal defects. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GEM 21S GROWTH–FACTOR ENHANCED MATRIX (U.S. Patent No. 5,124,316) from Biomimetic Therapeutics, Inc. (previously Biomimetic Pharmaceuticals, Inc.), and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 8, 2007, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of GEM 21S GROWTH–FACTOR

ENHANCED MATRIX 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 GEM 21S GROWTH–FACTOR ENHANCED MATRIX is 1,361 days. Of this time, 744 days occurred during the testing phase of the regulatory review period, while 617 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: February 28, 2002. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective February 28, 2002.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: March 12, 2004. FDA has verified the applicant's claim that the premarket approval application (PMA) for GEM 21S GROWTH–FACTOR ENHANCED MATRIX (PMA P040013) was initially submitted March 12, 2004.

3. *The date the application was approved*: November 18, 2005. FDA has verified the applicant's claim that PMA P040013 was approved on November 18, 2005.

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 987 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 July 31, 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 November 28, 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: May 7, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–10633 Filed 5–31–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0088]

Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines,'' dated May 2007. The guidance document provides to sponsors of pandemic influenza vaccines guidance on clinical development approaches to facilitate and expedite the licensure of influenza vaccines for the prevention of disease caused by pandemic influenza viruses. The guidance provides recommendations concerning clinical data to support traditional license approval of a biologics license application (BLA), or a BLA using the accelerated approval pathway. The guidance announced in this notice finalizes the draft guidance of the same title dated March 2006.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance 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: Kathleen E. Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines,'' dated May 2007. This document is intended to provide sponsors of pandemic influenza vaccines guidance on clinical development approaches to facilitate and expedite the licensure of influenza vaccines where the intended indication is for active immunization in persons at high risk of exposure to, or during a pandemic caused by, pandemic influenza viruses. The approaches in this guidance apply to both nonadjuvanted and adjuvanted hemagglutinin-based pandemic vaccines, including ''split virus,'' subunit, and whole virus inactivated vaccines propagated in embryonated chicken eggs or cell-culture, and to recombinant hemagglutinin-based protein vaccines, and DNA vaccines that express hemagglutinin. Also addressed are live attenuated influenza vaccines.

In the **Federal Register** of March 10, 2006 (71 FR 12366), FDA announced the availability of the draft guidance of the same title dated March 2006. FDA received several comments on the draft guidance. FDA considered those comments when finalizing the guidance. The guidance announced in this notice finalizes the draft guidance dated March 2006.

In the March 2006 draft guidance, FDA stated that clinical trial data could be submitted as a clinical efficacy supplement to an original BLA when the manufacturer has a U.S.-licensed trivalent inactivated or live attenuated influenza vaccine. After reviewing comments on the draft guidance and considering the matter further, we