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

revised our recommendations in the final guidance. All submissions for the initial licensure of a pandemic influenza vaccine should be submitted as BLAs, which will provide for a trade name and labeling specific to the pandemic vaccine. For sponsors with existing licensed seasonal inactivated or live attenuated influenza vaccines who intend to file a BLA for a pandemic influenza vaccine that utilizes the same manufacturing process, we would expect that the BLA would reference the original BLA, including the nonclinical and chemistry, manufacturing, and controls data in their original BLA. Manufacturers that do not have existing licensed influenza vaccines, or that do, but are seeking to license a pandemic influenza vaccine utilizing a different manufacturing process, may seek accelerated approval according to the provisions of 21 CFR 601.41.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338 and in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10499 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–0083]

Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated 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 Seasonal Inactivated Influenza Vaccines,'' dated May 2007. The guidance document is intended to provide to sponsors of seasonal inactivated influenza vaccines guidance on clinical development approaches to support a biologics license application (BLA). The guidance provides recommendations concerning clinical data to support traditional and accelerated license approvals for new seasonal inactivated influenza vaccines. The guidance announced in this notice finalizes the draft ''Guidance for Industry: Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccine'' 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 Seasonal Inactivated Influenza Vaccines,'' dated May 2007. The guidance is intended to provide to sponsors of seasonal inactivated influenza vaccines guidance on the clinical data needed to support a BLA. The approaches in the guidance apply to both nonadjuvanted and adjuvanted hemagglutinin-based seasonal 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.

Licensure of seasonal inactivated influenza vaccines may be sought through either traditional or accelerated pathways. The guidance provides recommendations for clinical data to support traditional and accelerated license approvals for new seasonal inactivated influenza vaccines.

In the **Federal Register** of March 10, 2006 (71 FR 12367), FDA announced the availability of the draft guidance entitled ''Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines'' dated March 2006. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The changes in the final guidance include a change from the term ''trivalent'' inactivated influenza vaccines to ''seasonal'' inactivated influenza vaccines. This change was made to provide flexibility for evolving public health needs, including the development of vaccines with either more than three or less than three antigens. In addition, editorial changes were made to improve clarity.