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 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 TARCEVA (erlotinib). TARCEVA is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TARCEVA (U.S. Patent No. 5,747,498) from Pfizer, 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 July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TARCEVA 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 TARCEVA is 2,653 days. Of this time, 2,541 days occurred during the testing phase of the regulatory review period, while 112 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*: August 16, 1997. The applicant claims October 10, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 16, 1997, 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*: July 30, 2004. The applicant claims January 20, 2004, as the date the new drug application (NDA) for TARCEVA (NDA 21–743) was initially submitted. The applicant claims this is the date it submitted the first module of NDA 21–743, which was submitted in several modules as part of a rolling NDA submission procedure. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the final module of the marketing application was submitted on July 30, 2004, which is considered to be the NDA initially submitted date.

3. *The date the application was approved*: November 18, 2004. FDA has verified the applicant's claim that NDA 21–743 was approved on November 18, 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 1,261 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 28, 2006. 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, 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: September 3, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–15987 Filed 9–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0383]

Draft Guidance for Industry on Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases,'' dated September 2006. This guidance provides recommendations to manufacturers of viral vaccines for the characterization and qualification of cell substrates and viral seeds used in the production of viral vaccines for human use. This draft guidance, when finalized, will replace the information specific to viral vaccines contained in the 1993 document, entitled ''Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals.''

DATES: Submit written or electronic comments on the draft guidance by December 28, 2006 to ensure their adequate consideration in preparation of the final guidance. General comments

on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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 draft 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 draft guidance document.

Submit written comments on the draft 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: Paul E. Levine, Jr., 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 draft document entitled ''Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases,'' dated September 2006. This draft guidance provides manufacturers of viral vaccines with recommendations for the characterization and qualification of cell substrates and viral seeds used for the production of viral vaccines for human use. These recommendations may be used to support a Biologics License Application or an application for an Investigational New Drug.

This draft guidance, when finalized, is intended to replace the information specific to viral vaccines, but does not replace information on other biological products, contained in the 1993 document entitled, ''Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals.'' This draft guidance, when finalized, is also intended to supplement recommendations on the production of viral vaccines for the prevention and treatment of infectious diseases, provided in the International Conference on Harmonisation (ICH) documents entitled ''Guidance for Industry: Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin'' dated September 1998 (63 FR 51074; September 24, 1998) and ''Q5D Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products'' (63 FR 50244; September 21, 1998).

The scope of this draft guidance document is limited to cell substrates of human and animal origins and does not cover characterization of unicellular organisms, such as bacteria or yeast. This draft guidance also applies to the characterization and qualification of viral seeds. This draft guidance does not supersede the general requirements for biologicals described in Title 21 Code of Federal Regulations (CFR), part 210, part 211, part 601, nor part 610.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent FDA's current thinking on the identified topic. It does not create nor 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

This draft 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). Most of the collections of information to which this draft guidance refers are covered by parts 601 (on BLAs) and 21 CFR part 312 (on INDs), and were approved under OMB Control No. 0910–0338 and 0910–0014, respectively. For the remaining referenced collections of information, those in 21 CFR 640.3 and 640.63 have been approved under OMB control numbers 0910–0116; those in part 211, including § 211.160(b), have been approved under OMB control number 0910–0139; and those in 21 CFR part 58 have been approved under OMB Control No. 0910–0119.

III. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft 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 the brackets in the heading of this document. A copy of the draft 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 draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or*http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–15963 Filed 9–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 1999D–0054, 2001D–0475, and 2003D–0364] (formerly Docket Nos. 99D–0054, 01D–0475, and 03D–0364, respectively)

Guidances on Providing Regulatory Submissions in Electronic Format; Withdrawal of Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research is announcing the withdrawal of three guidances for industry: ''Providing Submissions in Electronic Format—NDAs,'' ''Providing Regulatory Submissions in Electronic Format—ANDAs,'' and ''Providing Regulatory Submissions in Electronic Format: Annual Reports for NDAs and ANDAs.'' These guidances are being withdrawn because they are no longer consistent with more recent guidance and no longer reflect the agency's preferred format for receiving electronic submissions.

DATES: September 29, 2006.

FOR FURTHER INFORMATION CONTACT: Armando Oliva, Center for Drug Evaluation and Research (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1512, e-mail: *armando.oliva@fda.hhs.gov*, or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401