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 11, 2008. 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 10, 2008. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

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

[FR Doc. E8–10466 Filed 5–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0047] (formerly Docket No. 2007E–0139)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VECTIBIX 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 biological product.

ADDRESSES: Submit written or electronic 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product VECTIBIX (panitumumab). VECTIBIX is indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. Subsequent to this approval, the Patent and

Trademark Office received a patent term restoration application for VECTIBIX (U.S. Patent No. 6,235,883) from Amgen Fremont 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 May 16, 2007, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of VECTIBIX 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 VECTIBIX is 2,662 days. Of this time, 2,479 days occurred during the testing phase of the regulatory review period, while 183 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*: June 16, 1999. The applicant claims June 19, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 16, 1999, 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)*: March 29, 2006. The applicant claims December 15, 2005, as the date the original biologics license application (BLA) for VECTIBIX (BLA 125147/0) was initially submitted. However, FDA records indicate that BLA 125147/0 was submitted in several modules under the continuous marketing application pilot program. It is FDA's position that the approval phase begins when the marketing application is complete for review. The final module of the BLA making it complete for review was submitted on March 29, 2006.

3. *The date the application was approved*: September 27, 2006. FDA has verified the applicant's claim that BLA 125147/0 was approved on September 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 1,122 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 11, 2008. 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 10, 2008. 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: April 28, 2008.

Jane A. Axelrad,

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

[FR Doc. E8–10512 Filed 5–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0281]

Pilot Program to Evaluate Proposed Name Submissions; Concept Paper; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) are announcing a public technical meeting in preparation for a pilot program to enable pharmaceutical firms to evaluate proposed propriety names and submit the data generated from those evaluations to FDA for review. The purpose of the public technical meeting is to discuss a concept paper that describes the logistics of the pilot program, proposed recommendations for carrying out a proprietary name review, and the way FDA intends to review submissions made under the pilot program. FDA plans to formally issue the concept paper by the end of fiscal year (FY) 2008 and expects to begin enrollment in the pilot program in FY 2009.

DATES: The public meeting will be held on June 5 and 6, 2008, from 8:30 a.m. to 5 p.m. each day. Register to make a presentation at the meeting by May 23, 2008. See section III of this document for information on how to attend or present at the meeting. Submit any written or electronic comments regarding the concept paper and pilot program by July 7, 2008.

ADDRESSES: The public meeting will be held at the Crowne Plaza Hotel, 877 Georgia Ave., Silver Spring, MD 20910 (Metro: Silver Spring Station on the Red Line). Submit written or electronic requests to make a presentation at the meeting to Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**). A draft concept paper will be available soon.

Comment Submissions: Submit written comments 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Lana Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6196, Silver Spring, MD 20993, 301–796–0518, FAX: 301–847–8753, e-mail: *lana.pauls@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Medicine (IOM) in its 2006 report ''Preventing Medication Errors'' noted that ''[i]n particular, drug names that look or sound alike increase the risk of medication errors.'' FDA also has determined that many of the medication errors reported to the agency result from proprietary names that look or sound like the names of other medical products. Reducing the potential for medication errors due to proprietary name confusion is part of FDA's ongoing medical product risk management effort. In 2003, FDA held two public meetings that explored many of the issues involved in proprietary name review:

- The June 26, 2003, public meeting on ''Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential,'' Docket No. 2002N–0201 (68 FR 32529, May 30, 2003). Information about the meeting is available at *http://www.fda.gov/cder/meeting/drugNaming.htm*.
- The December 4, 2003, meeting of the Drug Safety and Risk Management Advisory Committee (68 FR 65075, November 18, 2003). Transcripts, presentations, and materials from the meeting are available at *http://www.fda.gov/ohrms/dockets/ac/cder03.html#DrugSafetyRiskManagement*.

FDA reviews proprietary names from both promotional and safety perspectives. The promotional review of proposed names considers whether the name functions to overstate the efficacy, minimize the risk, broaden the indication, make unsubstantiated superiority claims for the product, or is overly fanciful. The safety review of a proposed name is based on the findings of a Failure Modes and Effects Analysis of the proprietary name, and is focused on the avoidance of medical errors. FDA not only considers the potential for a name to be spelled similarly and/or sound similar to a currently marketed product or one that is in the approval pipeline, but also considers the potential for the proposed name to inadvertently function as a source of error for reasons other than look and sound-alike name confusion, for instance whether the abbreviation for the drug would be similar to the abbreviation of another drug product.

Consideration also is given to the proposed product's characteristics including its intended use, dosage form and strength, and route of administration, because the product characteristics provide a context for communication of the product name and ultimately determine the use of the product in the usual clinical practice setting. In addition, because product-name confusion can occur at any point in the medication use process, FDA considers the potential for confusion throughout the process, including product procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.

Currently, the data generated to access this information is internal to FDA. However, there have been a number of calls for industry to become involved in the name testing process including