eligibility for patent term restoration. In a letter dated April 22, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SELZENTRY 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 SELZENTRY is 1,524 days. Of this time, 1,294 days occurred during the testing phase of the regulatory review period, while 230 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*: June 6, 2003. The applicant claims June 10, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 6, 2003, 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*: December 20, 2006. The applicant claims December 19, 2006, as the date the new drug application (NDA) for SELZENTRY (NDA 22–128) was initially submitted. However, FDA records indicate that NDA 22–128 was submitted on December 20, 2006.

3. *The date the application was approved*: August 6, 2007. FDA has verified the applicant's claim that NDA 22–128 was approved on August 6, 2007.

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 73 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 April 13, 2009. 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 August 10, 2009. 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: February 2, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–2813 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0112]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VETMEDIN 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 animal 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.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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product VETMEDIN (pimobendan). VETMEDIN is indicated for the management of the signs of mild, moderate, or severe (modified NYHA Class II, III, or IV) congestive heart failure in dogs due to atrioventricular valvular insufficiency or dilated cardiomyopathy. VETMEDIN is indicated for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by-case basis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VETMEDIN (U.S. Patent No. 5,364,646) from Dr. Karl Thomae GmbH, 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 6, 2008, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of VETMEDIN 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 VETMEDIN is 2,751 days. Of this time, 2,715 days occurred during the testing phase of the regulatory review period, while 36 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the act (21 U.S.C. 360b(j)) became effective*: October 20, 1999. The applicant claims April 8, 1999, as the date the investigational new animal drug application (INAD) became effective. However, the date that a major health or environmental effects test is begun or the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, is the effective date for the INAD. According to FDA records, October 20, 1999, is the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the act*: March 26, 2007. FDA has verified the applicant's claim that the new animal drug application (NADA) for VETMEDIN (NADA 141–273) was initially submitted on March 26, 2007.

3. *The date the application was approved*: April 30, 2007. FDA has verified the applicant's claim that NADA 141–273 was approved on April 30, 2007.

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 1,492 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 April 13, 2009. 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 August 10, 2009. 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: February 2, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–2684 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0626]

Draft Guidance for Industry on Bioequivalence Recommendation for Vancomycin HCl; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to March 19, 2009, the comment period for the draft guidance for industry entitled ''Bioequivalence Recommendation for Vancomycin HCl'' that published in the **Federal Register** of December 16, 2008 (73 FR 76362). The draft guidance provides specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for vancomycin HCl capsules. FDA is taking this action in response to requests for an extension of the comment period to allow interested persons additional time to submit comments.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 19, 2009.

ADDRESSES: 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.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9314.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 16, 2008 (73 FR 76362), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendation for Vancomycin HCl.'' As described in the notice, the draft guidance further clarifies FDA's recommendations on the design of BE studies to support ANDAs for vancomycin HCl capsules. As also described in the notice, FDA will consider comments on the draft guidance as it finalizes its BE recommendations and addresses the complicated issues raised in ViroPharma Inc.'s (ViroPharma's) petitions for stay of action challenging FDA's revised BE recommendations (Docket No. FDA–2006–P–0007).

By letter dated December 19, 2008, ViroPharma requested that FDA extend the comment period for the draft guidance by 60 days. In support of its request, ViroPharma provided several reasons that explained why it believes an extension is appropriate, including that the issues involved with the draft guidance are complex and that the current 60-day comment period for the notice includes the months of December and early January when many interested persons are on holiday vacation. While ViroPharma acknowledges that the **Federal Register** notice announcing the availability of this draft guidance indicates that comments to guidance documents may be submitted at any time, ViroPharma states that it is essential that FDA be able to review and consider comprehensive comments from all stakeholders before finalizing the guidance. In addition, by letter dated January 23, 2009, the Biotechnology Industry Organization (BIO) requested that FDA extend the comment period for the draft guidance to provide interested persons additional time to submit comments, and by letter dated February 2, 2009, Akorn Inc. objected to BIO's extension request.

FDA has considered ViroPharma's and BIO's requests and Akorn's objection. FDA does not believe that a 60-day extension as requested by ViroPharma is warranted, but in response to ViroPharma's and BIO's requests, FDA is extending the comment period for the draft guidance for 30 days, until March 19, 2009. This extension will provide interested