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

persons with a total of 90 days to submit comments before FDA begins work on the final version of the guidance. The agency believes that this 30-day extension allows adequate time for interested persons to submit comments without significantly delaying FDA consideration of these important issues.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: February 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2800 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–2009–N–0664]

Food Labeling Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with The University of Arkansas, is announcing a public workshop entitled ''Food Labeling Workshop.'' This public workshop is intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on April 21, 2009, from 8 a.m. to 5 p.m., and on April 22, 2009, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Continuing Education Center, Two East Center St., Fayetteville, AR (located downtown).

Contact: David Arvelo, Small Business Representative, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, or e–mail: *david.arvelo@fda.hhs.gov*.

For information on accommodation options, contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479–575–4221, FAX: 479–575–2165, or e–mail: *seideman@uark.edu*.

Registration: You are encouraged to register by April 10, 2009. The University of Arkansas has a $250 registration fee to cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $350 payable to: ''The University of Arkansas.'' If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact*) at least 14 days in advance.

Registration Instructions: To register, please submit your name, affiliation, mailing address, phone/fax number, and e–mail, along with a check or money order for $250 payable to the ''The University of Arkansas.'' Mail to: Institute of Food Science & Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested at cost through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers and startups originating from the area covered by the FDA Dallas District Office. The SWR SBR presents these workshops to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the SBR Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about obesity and food allergens. Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling requirements, (3) health and nutrition claims, (4) the Food Allergen Labeling and Consumer Protection Act of 2004, and (5) special labeling issues such as exemptions. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and increase voluntary compliance.

Dated: January 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2811 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–2009–N–0664]

Food Protection; Public Workshop

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in co-sponsorship with the University of Arkansas Institute of Food