

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0626]

DDM

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Certifier A. Corbin

Draft Guidance for Industry on Bioequivalence Recommendation for Vancomycin HCl; Extension of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is extending to March 19, 2009, the comment period for the draft guidance for industry entitled “Bioequivalence Recommendation for Vancomycin HCl” that published in the **Federal Register** of December 16, 2008 (73 FR 76362). The draft guidance provides specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for vancomycin HCl capsules.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 19, 2009.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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In the **Federal Register** of December 16, 2008 (73 FR 76362), FDA published a notice announcing the availability of a draft guidance for industry entitled “Bioequivalence Recommendation for Vancomycin HCl.” As described in the notice, the draft guidance further clarifies FDA’s recommendations on the design of BE studies to support ANDAs for vancomycin HCl capsules. As also described in the notice, FDA will consider comments on the draft guidance as it finalizes its BE recommendations and addresses the complicated issues raised in ViroPharma Inc.’s (ViroPharma’s) petitions for stay of action challenging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: 2/4/09
February 4, 2009.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

JS
2/4/09

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