

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0240]

Draft Guidance for Industry on Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention; Availability; Extension of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is extending to October 28, 2005, the comment period for the draft guidance for industry entitled “Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention.” The draft guidance is intended to assist sponsors in conducting clinical trials for drug products that treat or prevent gingivitis. It addresses specific protocol design elements as well as general concerns about drugs for this indication. FDA published a notice of availability of the draft guidance, with a comment period that closes on August 29, 2005. FDA is taking this action in response to a request for extension of the comment period to allow interested persons additional time to review the draft guidance and submit comments.

DATES: Submit written or electronic comments on the draft guidance by October 28, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Frederick Hyman, Center for Drug Evaluation and Research (HFD-540), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2020.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 28, 2005 (70 FR 37102), FDA published a notice announcing the availability of a draft guidance for industry entitled “Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention.” This guidance is intended to assist sponsors in conducting clinical trials for drug products that treat or prevent gingivitis. The guidance document provides assistance in several ways. It addresses specific design elements such as choosing inclusionary and exclusionary criteria, selecting relevant endpoints, assessing gingivitis, determining the clinical significance of the effect, and collecting meaningful safety data. It also provides comments on general concerns (e.g., prevention versus treatment claims, over-the-counter versus prescription status, special population enrollment, and nonclinical development issues related to products that are intended for administration within the oral cavity for the treatment or prevention of gingivitis). The initial comment period closes on August 29, 2005.

II. Extension of Time

On July 15, 2005, the Consumer Healthcare Products Association requested a 60-day extension beyond the August 29, 2005, deadline for the submission of comments. The request stated that additional time is needed to assemble a comprehensive submission that requires coordinating extensive input from representatives of their member companies. FDA considers an extension of time for submission of comments to be in the public interest. Accordingly, FDA is extending the comment period for 60 days to October 28, 2005, as requested.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments 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. 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/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S