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.

Dated: September 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23866 Filed 9–30–09; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0447]

Draft Guidance for Industry on Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''*Helicobacter pylori*-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in clinical drug development for the treatment of adults with duodenal ulcers caused by *H. pylori* for the reduction of duodenal ulcer recurrence. Specifically, this guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs to support antimicrobial-containing *H. pylori* treatment regimens.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 4, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joette M. Meyer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6130, Silver Spring, MD 20993–0002, 301–796–1600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''*Helicobacter pylori*-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in clinical antimicrobial drug development for the treatment of adults with duodenal ulcers caused by *H. pylori* for the reduction of duodenal ulcer recurrence. This guidance, when finalized, will supersede advice given in the draft guidance for industry entitled ''Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products,'' published in 1997, which contains section V, regarding indication 25 *H. pylori*.

This draft guidance pertains to development of drugs for the treatment of adults with duodenal ulcers. It does not address treatment of children, or those with other conditions also associated with *H. pylori*, including gastric ulcers and non-ulcer dyspepsia.

Currently approved regimens for the treatment of adults with duodenal ulcers consist of multiple drugs used in combination. We anticipate that drug development for new drugs or regimens will occur in one of three ways: (1) Substitution of a new drug for one component of an approved regimen, (2) addition of a new drug to an approved regimen, and (3) development of a new regimen not studied previously. The draft guidance provides information on the type of study design and supportive information that should be provided for each of these development paths. Information is also provided regarding microbiological procedures and use of diagnostic testing to determine subject evaluability.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment of *H. pylori*-associated duodenal ulcer disease in adults. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: September 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23875 Filed 10–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0247]

Food and Drug Administration Transparency Task Force; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a second public meeting to discuss issues related to transparency at the agency. The purpose of this public meeting is to receive detailed and in-depth comments on three specific issues related to