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 1,826 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 December 4, 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 April 5, 2010. 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: June 23, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–23900 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–D–0470]

Draft Guidance for Industry and FDA Staff; the Scope of the Prohibition Against Marketing a Tobacco Product in Combination With Another Article or Product Regulated Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act.'' This guidance is intended for manufacturers, retailers, importers, and FDA staff. The Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), states ''A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).'' The guidance discusses certain activities that FDA believes do or do not fall within the scope of the prohibition. The guidance is not intended to be an exhaustive analysis of all activities that may or may not fall within the scope of the prohibition.

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 document entitled ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–595–7946. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 0850–3229, 301–796–4800, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the FSPTCA (Public Law 111–31) into law. The FSPTCA amended the FDCA (21 U.S.C. 301 *et seq.*) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201(rr)(4) of the FDCA, as amended by the FSPTCA, states ''A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).''

This guidance discusses certain activities that FDA believes do or do not fall within the scope of the prohibition. The guidance is not intended to be an exhaustive analysis of all activities that may or may not fall within the scope of the prohibition.

II. Significance of Guidance

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 ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act.'' 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. The guidance document may be accessed at the Center for Tobacco Products' Web site at *http://www.fda.gov/tobaccoproducts*. This guidance document is also available at *http://www.regulations.gov*. To receive ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act,'' you may either send an e-mail request to *michele.mital@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–595–7946 to receive a hard copy.

IV. 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.

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