

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]

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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Draft Guidance for Industry on *Helicobacter pylori*-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “*Helicobacter pylori*-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors in clinical drug development for the treatment of adults with duodenal ulcers caused by *H. pylori* for the reduction of duodenal ulcer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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 4, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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

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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

transparency at FDA. The topics to be covered are early communication about emerging safety issues concerning FDA-regulated products, disclosure of information about product applications that are abandoned (which means that no work is being done or will be undertaken to have the application approved) or withdrawn by the applicant before approval, and communication of agency decisions about pending product applications.

DATES: The public meeting will be held on November 3, 2009, from 9 a.m. to 3 p.m. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on October 27, 2009. Submit electronic or written comments by November 6, 2009.

ADDRESSES: The public meeting will be held at the National Transportation Safety Board Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets at the heading of this document. Submit electronic registration by e-mail to Transparency.Meeting@fda.hhs.gov.

For Registration to Attend and/or to Participate in the Meeting: If you wish to attend the public meeting, you must register by e-mail (see **ADDRESSES**) by close of business on October 27, 2009. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) telephone number, and (6) e-mail address.

At the time of registration, if you wish to participate in one of the three planned discussion groups, you must indicate which discussion group(s), in rank order (see section **III. ISSUES FOR DISCUSSION**). Please also submit a brief statement that describes your experience with the discussion topic and/or the general nature of what you would like to present about the discussion topic. The Transparency Task Force ("Task Force") is seeking participants interested in engaging in an in-depth discussion about the considerations and principles the agency should consider with respect to communicating to the public about each of the issues outlined below (see section **III. ISSUES FOR DISCUSSION**).

Each discussion group will include 4 to 6 people. Only one participant from an organization or company will be assigned to a discussion group. FDA

will attempt to have a range of stakeholders participate in each discussion group. Participants will be contacted prior to the meeting with the approximate time the discussion group is scheduled to begin. Others in attendance at the public meeting will have an opportunity to listen to the discussion and comment on the issues discussed during the public comment period that will occur after each discussion group.

There is no fee to register for the public meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registration on the day of the public meeting will be permitted on a space-available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Afia Asamoah (see **FOR FURTHER INFORMATION CONTACT**) by October 27, 2009.

FOR FURTHER INFORMATION CONTACT: Afia Asamoah, Office of the Commissioner, Food and Drug Administration, Bldg. 1, rm. 2220, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4625, FAX: 301-847-3531, Afia.Asamoah@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 21, 2009, President Obama's first full day in office, the President issued a memorandum to the heads of executive departments and agencies on transparency and openness in government. The memorandum expressed the Administration's commitment to achieve "an unprecedented level of openness in Government" and instructed executive departments and agencies to solicit public input to identify information of greatest use to the public. Executive departments and agencies were also charged with harnessing new technologies to make information about agency operations and decisions available online and readily available to the public.

In response to the Administration's commitment to promote transparency in government, FDA formed an internal Task Force to consider how to make FDA and its processes more transparent to the public. The Task Force is soliciting input from the public to develop recommendations for making useful and understandable information about FDA activities and decisionmaking more readily available to the public in a timely manner and in a user-friendly format, while appropriately protecting confidential information. To solicit public input on

improving agency transparency, the Task Force established a public docket, launched an online blog, and held a public meeting in June. At the first public meeting, the Task Force posed six questions about ways in which the agency should provide information to the public about what FDA is doing, the bases for the agency's decisions, and the processes used to make agency decisions.¹

Based on the comments received to date, the Task Force is holding a second public meeting to solicit in-depth and detailed comments on three specific issues related to transparency at the agency.

II. Second Public Meeting

The objective of the second public meeting on transparency is for the Task Force to receive public input and hear different points of view about the agency's communications about, and public disclosures of information about, the following issues:

(1) Emerging safety issues concerning FDA-regulated products,

(2) Product applications that are abandoned (no work is being done or will be undertaken to have the application approved) or withdrawn by the applicant before approval, and

(3) Agency decisions about pending product applications.

The Task Force is interested in focused, detailed comments about the considerations and principles the agency should assess regarding its communications to the public about the topics outlined in the previous paragraphs.

The second public meeting will be conducted as a series of three moderated discussion groups covering these three topics. The specific topic for each discussion will be presented in the form of a case study. Only one discussion group will be held at a time. Following each moderated discussion, Task Force members may ask questions of the participants in each discussion group. Others in attendance at the public meeting then will have an opportunity to comment on the issues discussed during the public comment period that will occur after each discussion group.

At least 7 days in advance of the meeting, the initial scenarios of the case studies for each of the three topics will be made available on the Internet. The initial scenarios will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov>. The initial scenarios will also be available on

¹ See 74 FR 26712, June 3, 2009.

FDA's Web site at <http://www.fda.gov/transparency> along with the agenda for this meeting. The complete case studies will be available in the same locations after the public meeting.

III. Issues for Discussion

The discussion of the three issues described in the following section of this document should not be limited by current statutes or regulations, as the proposals the Task Force develops may include recommendations for changes to current law.

A. Emerging Safety Issues Concerning FDA-Regulated Products

When FDA receives safety information associated with a marketed FDA-regulated product, e.g., medical device, drug, biologic, dietary supplement, cosmetic, or food (including ingredients and food additives), FDA evaluates the information in deciding whether and what actions to take, such as regulatory action regarding the product. FDA will continue to receive, gather, and evaluate additional information to further inform its decisions.

During this process, while still evaluating the situation, FDA may communicate with the public based on the agency's current analysis of the available information about the situation. For example, the agency may issue an early communication about its ongoing safety review of a drug, device, or biologic, or may issue an early communication advising consumers not to eat a certain type of food that may be linked to a foodborne illness or to stop using a certain dietary supplement that may be associated with adverse events.

The Task Force is interested in discussing the principles the agency should use when deciding whether to issue an early communication about a potential problem with an FDA-regulated product. For example, when is it appropriate, or not appropriate for the agency to advise the public about a possible, but unconfirmed foodborne illness outbreak or to issue an early communication about an emerging safety issue with a medical product, dietary supplement, or cosmetic? If appropriate, how should this information be conveyed to the public so that it is useful and does not cause unfounded or unnecessary concern about the product? And what mechanisms (e.g., Internet, mass media, cell phones, direct outreach to health professional and patient organizations) should FDA use to effectively reach the target audiences in a timely manner?

B. Product Applications That Are Abandoned (Which Means That No Work is Being Done or Will Be Undertaken to Have the Application Approved) or Withdrawn By the Applicant Before Approval

The Task Force is interested in discussing the principles and considerations the agency should apply to disclosure of data contained in product applications that are abandoned during the approval process or withdrawn before approval by the applicant. The Task Force would also like to receive comments on whether the considerations governing treatment of these data should depend on the reason the product application was abandoned or withdrawn.

C. Communicating Agency Decisions About Pending Product Applications

The Task Force is interested in discussing what information about pending product applications should be disclosed. Should the agency inform the public when:

- A marketing application seeking approval of a drug or biologic is submitted to the agency for review?
- A marketing application seeking approval or clearance of a medical device is submitted to the agency for review?

When the agency does not approve a marketing application for a drug or biologic, it issues a letter that informs the applicant of FDA's determination not to approve the application in its current form, identifying all apparent deficiencies in the application. Should the agency disclose to the public a determination not to approve a marketing application for a drug or biologic? What, if any, information should the agency disclose about the determination not to approve the application? What, if any, information contained in the response letter should the agency disclose? What principles should the agency apply in making these determinations?

When the agency does not approve a premarket application (PMA) for a medical device, it may issue a "not approvable" letter that informs the applicant of FDA's determination not to approve the application in its current form. When the agency does not clear a device submitted through the 510(k) process, a "not substantially equivalent" (NSE) letter is issued to the applicant. Should the agency disclose to the public a determination not to approve or clear a marketing application for a medical device? What, if any, information should the agency disclose about the determination not to approve or clear

the application? What, if any, information contained in the not approvable letter or the NSE letter should the agency disclose? What principles should the agency apply in making these determinations?

IV. Request for Comments

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments (see **ADDRESSES**). Submit a single copy of electronic comments to <http://www.regulations.gov> 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.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: September 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Agency Information Collection Activities: Delivery Ticket

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651-0081.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Delivery