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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier J. Corbin

[Docket No. FDA-2008-N-0567]

Designating Additions to the Current List of Tropical Diseases in the Food and Drug Administration Amendments Act; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain input on adding additional diseases to the list of tropical diseases recognized under the Food and Drug Administration Amendments Act (FDAAA), which adds a new section to the Federal Food, Drug, and Cosmetic Act (the act). The new section authorizes FDA to award priority review vouchers to sponsors of certain tropical disease product applications that meet the criteria specified by the act. The new section lists diseases considered to be "tropical diseases" for the purposes of this legislation, and provides for expansion of the list to include diseases meeting certain criteria. This public meeting is being held to obtain comments from the public on the criteria that should be used to determine whether an infectious disease should be added to the list, and to elicit suggestions for adding specific diseases.

DATES: The public hearing will be held on December 12, 2008, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early. Submit written or electronic requests for oral presentations and comments by November 17, 2008. Written or electronic comments will be accepted after the hearing until February 6, 2009.

ADDRESSES: The public hearing will be held at the National Transportation Safety Board Boardroom and Conference Center at 429 L'Enfant Plaza, SW, Washington, DC 20594. 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>. All comments should be identified with the docket number found in brackets in the heading of this document. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 30 days after the hearing.

FOR FURTHER INFORMATION CONTACT: Jeff O'Neill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-0777, FAX: 301-847-8753, e-mail: jeff.o'neill@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The new section, section 524 of the act (21 U.S.C. 360n), is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world. Section 524 provides a means by which the holder of an application for a tropical disease product may be eligible to receive a priority review voucher upon approval of that application. This voucher entitles the sponsor to be granted a priority review for a subsequent application of a drug or biologic, submitted under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (42 U.S.C. 262), of the sponsor's choosing that would not otherwise be eligible for a priority review. FDA is

committed to a goal of reviewing and taking an action within 6 months of receipt on 90% of applications that have been granted a priority review (see <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>).

To be granted a priority review voucher, the tropical disease application must meet all of the following criteria:

- The application must be a human drug application as defined in section 735(1) of the act (21 U.S.C. 379g(1)).
- The application must be for the prevention or treatment of a tropical disease.
- The tropical disease application must be eligible for priority review.
- The tropical disease application must be for “a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351 of the Public Health service Act.”

After being granted a priority review voucher, the owner of the voucher may transfer it to another sponsor. The sponsor intending to redeem a priority review voucher must notify the agency at least 365 days prior to submission of the application for which the voucher is to be redeemed. This notification constitutes a legally binding agreement to pay a supplemental user fee that is mandated by the act to be applied to an application using a priority review voucher.

The act identifies the following list of specific diseases that qualify as “tropical diseases” (section 524(a)(3)):

- Tuberculosis
- Malaria
- Blinding trachoma
- Buruli Ulcer

- Cholera
- Dengue/Dengue haemorrhagic fever
- Dracunculiasis (guinea-worm disease)
- Fascioliasis
- Human African trypanosomiasis
- Leishmaniasis
- Leprosy
- Lymphatic filariasis
- Onchocerciasis
- Schistosomiasis
- Soil transmitted helminthiasis
- Yaws

The legislation allows for the addition to this list of “any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary.”

This hearing is being convened to encourage feedback from the public regarding criteria that should be used to determine the eligibility of an infectious disease for inclusion in this list and the process that should be used to make additions to the list. FDA staff will provide an overview of section 524 at the beginning of the meeting.

II. Scope of the Hearing

FDA is interested in obtaining public comment on the following issues related to the tropical diseases listed in section 524 of the act:

1. Should other infectious diseases be added at this time to the list of tropical diseases that are eligible for receiving a priority review voucher? If so, are there specific infectious diseases that you believe should be added?

Provide justification for your recommendations, consistent with the act's requirements for inclusion of additional tropical diseases.

2. To be added to the list of tropical diseases, the act requires that the disease meet the following criteria:

- There must be no significant market in developed nations
- It must disproportionately affect poor and marginalized populations.

How should this language be interpreted?

3. What procedures, prior to the rulemaking required by section 524(a)(3), would facilitate the process for adding infectious diseases to the list of tropical diseases?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

If you wish to make an oral presentation during the hearing, you must submit a written or electronic request by close of business on Monday, November 17, 2008. You must provide your name, title, business affiliation (if applicable), address, and type of organization you represent (e.g., industry, consumer organization), and a brief summary of the presentation (including the discussion topic(s) that will be addressed to Jeff O'Neill at *jeff.o'neill@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**). Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to the contact person (see **FOR FURTHER INFORMATION CONTACT**). We will file the hearing schedule with the Division of Dockets Management (see **ADDRESSES**), indicating the order of presentation and time allotted to each person. We will also mail or fax the schedule to each participant before the hearing. Participants are encouraged to arrive early to ensure the designated order of presentation.

Attendees who do not wish to make an oral presentation do not need to register. The meeting is free and seating will be on a first-come, first-served basis.

The hearing will be transcribed as stipulated in § 15.30(b). Transcripts will be available 45 days after the hearing on the Internet at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hard copy or on CD-ROM after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

IV. Request for Comments

Interested persons may submit to the *Division of Dockets Management* (see **ADDRESSES**) written or electronic comments for consideration. Persons who wish to provide additional materials for consideration should file these materials with the *Division of Dockets Management*. You should annotate and organize your comments to identify the specific questions identified by topic to which they refer. 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 *Division of Dockets Management* between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: 10/29/08
October 29, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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