DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0587]

Draft Guidance for Industry on Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment or prevention of neglected diseases of the developing world. Specifically, this guidance addresses FDA's current thinking regarding the overall drug development program for the treatment or prevention of neglected tropical diseases (NTDs), including clinical trial designs and internal review standards to support approval of drugs.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 22, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention.'' This guidance addresses section 740 of the Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act, 2010 (Pub. L. 111–80), dated October 21, 2009, that directed FDA to provide guidance in the form of general recommendations and regulatory considerations for drugs being developed for the treatment or prevention of NTDs. NTDs, as defined in section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)), are infectious diseases that generally are rare or absent in developed countries, but are often widespread in developing countries. The availability of new drugs that are safe and effective for treatment or prevention of NTDs could provide public health benefit for overall global health.

The purpose of this draft guidance is to provide recommendations to sponsors and investigators who are involved in the development of drugs for the treatment or prevention of NTDs. This guidance is intended to clarify the regulatory requirements for drug approval in the United States as well as the internal review standards for drugs for NTDs. This guidance is directed at sponsors who lack general knowledge about drug development issues. Potential sponsors should understand that: (1) FDA will review and comment on clinical development programs for NTDs under an investigational new drug application submission, regardless of where the clinical development will take place; (2) FDA can approve a drug for treatment of an NTD not endemic in the United States; (3) the regulatory pathways and internal review standards for approval of drugs for NTDs are the same as for approval of drugs for diseases endemic in the United States; and (4) FDA is committed to exercising its regulatory authorities to facilitate access to therapies that can help reduce morbidity and mortality associated with NTDs.

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 this topic. 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 part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21630 Filed 8–23–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which