



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0587]

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 guidance for industry entitled "Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention." The purpose of the guidance is to assist sponsors in the development of drugs for the treatment or prevention of neglected tropical diseases (NTDs). This guidance represents the FDA's current thinking regarding drug development for the treatment or prevention of NTDs, including clinical trial designs and internal review standards to support approval of drugs. This guidance finalizes the draft guidance issued August 24, 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 guidance document.

Submit electronic comments on the 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 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 development of drugs for the treatment or prevention of NTDs as defined in section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)).

NTDs are infectious diseases that are generally 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.

This guidance addresses general issues in drug development and implementation of clinical trials for NTDs. FDA will review and comment on drug development plans and will review new drug applications or biologics license applications for new drugs for NTDs, regardless of where the clinical development program takes place. Specifically, the guidance provides a general overview of nonclinical development considerations, as well as clinical development considerations and regulatory paradigms. Other activities in the Center for Drug

Evaluation and Research that pertain to NTDs are summarized in the guidance. Listings of guidance documents that are most relevant to drug development for NTDs are included in the guidance.

This guidance finalizes the draft guidance issued August 24, 2011. Comments on the draft guidance were considered while finalizing this guidance. Specifically, changes from the draft guidance include descriptions of new regulatory designations (Qualified Infectious Disease Product; Breakthrough Therapy).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing drugs for the treatment or prevention of neglected tropical diseases of the developing world. 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 and 21 CFR part 314 have been approved under OMB control numbers 0910-0014 and 0910-0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

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: July 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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