

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007D-0212]

6-6-07  
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Certifier L. CLAWSON  
DAM

**Draft Guidance for Industry on Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis." This draft guidance addresses issues regarding the development of therapy for prophylaxis and treatment of malaria. Specific topics include recommendations for preclinical development, clinical trial study design, the use of microbiological testing during clinical trials, and statistical considerations.

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing cd06176

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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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Leonard Sacks, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6178, Silver Spring, MD 20993-0002, 301-796-1600.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis.” Malaria is a major global problem with the greatest burden of disease and mortality occurring in developing countries. Although cases of malaria are uncommon in the United States, antimalarial drugs have significant public health importance in the United States: Antimalarial prophylaxis is used extensively by U.S. travelers and by U.S. citizens residing in or deployed to endemic areas (e.g., military personnel).

This guidance addresses the development of therapy for the prophylaxis and treatment of malaria. Overall aspects of a developmental program for antimalarial therapy are discussed. Specific topics include recommendations for preclinical development, clinical trial study design, the use of microbiological testing during clinical trials, and statistical considerations.

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 drug and nonvaccine

biological products for the treatment and prophylaxis of malaria. 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.

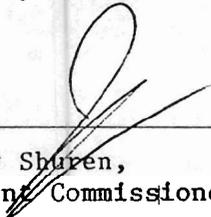
**II. Comments**

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.

**III. Electronic Access**

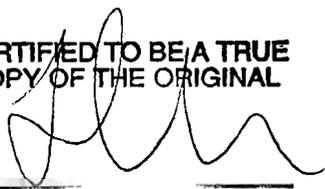
Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ohrms/dockets/default.htm> or <http://www.fda.gov/cder/guidance/index.htm>.

Dated: 5/26/07  
May 26, 2007.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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