have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 31, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–10996 Filed 6–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0212]

Draft Guidance for Industry on Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis; Availability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

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis.'' This draft guidance addresses issues regarding the development of therapy for prophylaxis and treatment of malaria.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by September 5, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: May 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11001 Filed 6–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Food Quality Indicator Device

AGENCY: Food and Drug Administration, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the Food and Drug Administration, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the invention embodied in U.S. Patent 7,014,816, issued March 21, 2006, entitled ''Food Quality Indicator Device'' [E–093–1997/0–US–03] and foreign counterparts; to Litmus, LLC, having a place of business in Little Rock, AR. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the manufacture, use, distribution and sale of the Food Quality Indicator Device as claimed in the licensed patent rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 6, 2007 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments,