during the regulatory review period by December 4, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

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

Dated: May 2, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–10915 Filed 6–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–1232] (formerly 98D–1232)

Guidance for Industry and Food and Drug Administration Staff; Assayed and Unassayed Quality Control Material; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry and FDA staff entitled ''Assayed and Unassayed Quality Control Material.'' The guidance describes FDA's current practices concerning assayed an unassayed quality control material, including information to include in a 510(k) for assayed quality control material, as well as labeling recommendations.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Assayed and Unassayed Quality Control Material'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0396.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations to manufacturers regarding preparation of premarket notifications and labeling for quality control (QC) material. These materials are intended to monitor reliability of a test system and help minimize reporting of incorrect test results. They are often the best source of ongoing feedback that a laboratory has to monitor whether results reported to physicians are sufficiently reliable. QC materials may be marketed together with a specific test system, or alternatively, for more general use.

Both assayed and unassayed QC materials are discussed in the guidance document. Both types of QC materials are subject to FDA's Quality System Regulation (part 820 (21 CFR part 820)) and labeling regulation (§ 809.10 (21 CFR 809.10)). However, most types of unassayed QC materials are exempt from premarket notification. (See ''Classification and Identification of QC Material'' of the guidance document for exceptions.) Although premarket notifications are number required for unassayed QC materials, some aspects of this guidance document concerning labeling, stability, and matrix effects are still relevant for these materials.

The draft version of this guidance was issued February 3, 1999. FDA received one set of comments on the draft guidance document during the comment period. The document reflects FDA's consideration of the comments and has also been updated to provide clarification as needed.

II. Significance of Guidance

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 assayed and unassayed quality control material. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Assayed and Unassayed Quality Control Material; Availability,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (2231) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 610 have been approved under OMB control number 0910–0206; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0120; the collections of information in § 809.10

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,