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Draft Guidance for Industry on Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis.'' This draft guidance addresses issues regarding the development of therapy for prophylaxis and treatment of malaria.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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by September 5, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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

and other materials relating to the contemplated exclusive license should be directed to: Adaku Nwachukwu, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; E-mail: *madua@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology relates to an effective way to monitor food quality and freshness in real time. The major factor for food spoilage is the release of volatile bases due to the action of enzymes contained within the food or produced by microorganisms, such as bacteria, yeasts and molds growing in the food. The rate of release of such bases depends on food's storage history. In this technology, a reactive dye locked in a water-repellent material reacts with the bases released during food decomposition, and changes color. Thus a rapid and informed decision can be made about quality of food and its shelf life under the storage conditions used. Since the detection is based on biological processes that are the root cause for food spoilage, these indicators are much more reliable.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 21, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–10963 Filed 6–6–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substances Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMSHA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMSHA Reports Clearance Officer on (240) 276–1243.

Project: Community Mental Health Services Block Grant Application Guidance and Instruction, FY 2008–2010 (OMB No. 0930–0168)—Revisions

Sections 1911 through 1920 of the Public Health Service Act (42 U.S.C. 300x through 300x–9) provide for annual allotments to assist States to establish or expand an organized, community-based system of care for adults with serious mental illnesses and children with serious emotional disturbances. Under these provision of the law, States may receive allotments only after an application is submitted and approved by the Secretary of the Department of Health and Human Services.

For the FY 2008–2010 Community Mental Health Services Block Grant application cycle, SAMSHA will provide States guidance and instructions to guide development of comprehensive State applications/plans and implementation reports. Proposed revisions to the guidance include:

(1) The integration of mental health transformation as a guiding principle in the development of State mental health plans. State plans for FY 2008–2010 will describe State mental health transformation efforts and activities within the context of the five (5) legislative criteria, identify mental health transformation activities funded by the MHBG and other State funding sources, identify activities of the State mental health planning council that contribute to and support State transformation efforts, include one State transformation performance indicator in the plan, and include a description of the services provided to older adults under criterion 4 of the State's plan.

(2) The introduction of the Web Block Grant Application System (WebBGAS). WebBGAS enables States to submit applications/plans, and implementation reports electronically thus reducing the burden of paperwork required for submission, revision, and reporting purposes. In FY 2008, all States and Territories will be encouraged to submit State plans using WebBGAS. Other advantages to using WebBGAS include:

- Eliminating redundancy in data entry by pre-populating the States' previous year data in the current year's plans and implementation reports.
- Standardizing Mental Health Block Grant data for reporting and quantitative analysis.
- Allowing the States' mental health planning councils to have access to state plans and implementation reports throughout the FY as a means to enable councils to meet their Federal mandate of reviewing the plans and providing recommendations to the State.
- Adhering to the Federal Government's e-governments and e-grants initiatives, where applicable.

(3) A requirement for States to report nine CMHS National Outcome Measures (NOMS) for mental health. All nine measures are derived from tables in the Uniform Reporting System (URS) which was developed in collaboration with the States. Four (4) of the nine measures were established, in concert with OMB PART, to support the long-term goals of the Mental Health Block Grant program and SAMSHA's Government Results and Performance Act (GPRA) measures. The nine CMHS measures are:

- Increased access to services
- Reduced utilization of psychiatric inpatient beds for 30 and 180 days
- Number of evidenced-based practices and number of persons served in these programs
- Client perception of care
- Increased/retained employment or returned to/stayed in school
- Decreased criminal justice involvement
- Increased stability in housing
- Increased social supports and social connectedness, and
- Improved level of functioning.

Two of the NOMS, Increased Social Supports and Social Connectedness, and Improved Functioning, are currently under development at SAMSHA. States that are unable to report data on these or other indicators will be required to describe their current reporting capacity and efforts underway to make collection of the data possible.

(4) Revisions to tables in the Uniform Reporting System (URS). Since FY 2001, States have reported annual data on the public mental health system to the MHBG Program through 21 tables in the URS. For the past three years, CMHS worked collaboratively with States, using the Data Infrastructure Grant (DIG) process, to refine the data and make