TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Respondents	Total Annual Respondents	Hours per Respondent	Total Hours
54	1	54	1.5	81

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 23, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–7679 Filed 3–28–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1494]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Classification/Reclassification; Restricted Devices: Analyte Specific Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Classification/Reclassification; Restricted Devices: Analyte Specific Reagents'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 2001 (66 FR 1140), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0361. The approval expires on March 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: March 23, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1718]

Guidance for Industry on Monoclonal Antibodies Used as Reagents in Drug Manufacturing; 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 ''Monoclonal Antibodies Used as Reagents in Drug Manufacturing.'' This guidance is intended to provide recommendations for sponsors and applicants of new drug applications (NDA's), abbreviated new drug applications (ANDA's), biologics license applications (BLA's), their supplements, or investigational new drug applications (IND's) on information that should be included in applications when monoclonal antibodies (mAb's) are used as reagents in the manufacture of drug substances regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), 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 guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Eugenia M. Nashed, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050, or Kurt A. Brorson, Center for Biologics Evaluation and Research (HFM–561), 8800 Rockville Pike, Bethesda, MD 20892–0029, 301–827–0661.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Monoclonal Antibodies Used as Reagents in Drug Manufacturing.'' This guidance focuses on the chemistry, manufacturing, and control (CMC) issues that should be addressed in NDA's, ANDA's, BLA's, their supplements, or IND's. This document is not intended to cover mAb's used as diagnostics, radiolabeled imaging agents, or therapeutic products. In the **Federal Register** of June 24, 1999 (64 FR 33868), FDA announced the availability of a draft version of this guidance. The June 1999 document gave interested persons an opportunity to submit comments through September 22, 1999. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of public input during the comment period, the final guidance is clearer and more concise than the draft version.

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on monoclonal antibodies used as reagents in drug manufacturing. 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, at any time, submit written comments on the guidance to the Dockets Management