

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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]
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Dated: March 23, 2001.
William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.
 [FR Doc. 01-7678 Filed 3-28-01; 8:45 am]
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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

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>.

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

Branch (address above). Two copies of any comments 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. The guidance and received comments are available for public examination in the Dockets Management Branch 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 <http://www.fda.gov/cder/guidance/index.htm>.

Dated: March 22, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-7680 Filed 3-28-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Director's Council of Public Representatives.

Date: May 1, 2001.

Time: 8 a.m. to 4:30 p.m.

Agenda: Among the topics proposed for discussion are: (1) Research involving children; (2) diabetes; (3) nursing research; and (4) human research protections.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20892.

Contact Person: Jennifer E. Gorman, NIH Public Liaison/COPR Coordinator, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892, (301) 435-4448, gormanj@od.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment

Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency)

Dated: March 22, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-7817 Filed 3-28-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given on a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: April 16-18, 2001.

Time: 8:30 PM to 5 PM.

Agenda: Report of Director NCI and discussion; "How Advocacy Groups Work" session; Working Group Update; Discussion of priorities of the DCLG.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Elaine Lee, Acting Executive Secretary, Office of Liaison Activities, National Institutes of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594-3194.

This meeting is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/dclg/delg.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support;

93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 23, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-7813 Filed 3-28-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings. The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-6(m3).

Date: April 24, 2001.

Time: 7 p.m. to 11 p.m.

Agenda: To review and evaluate grant applications

Place: Ritz-Carlton Pentagon City, 1250 S. Hayes Street, Arlington, VA 22202.

Contact Person: Neal A. Musto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 651, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892-6600, (301) 594-7798.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-6(M1).

Date: April 25, 2001.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Neal A. Musto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 651, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892-6600, (301) 594-7798.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition