ANNUAL BURDEN ESTIMATES

| Instrument | No. of respondents | No. of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| IV–E–1 | 52 | 4/YR | 25 | 5200 |
| Estimated Total Annual Burden Hours | | | | 5200 |

*Additional Information*

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

*OMB Comment*

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 23, 2001.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 01–7751 Filed 3–28–01; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0135]**

### Agency Emergency Processing Under OMB Review; Focus Group Study of Radiation Disclosure Statement Options for Foods Treated With Ionizing Radiation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is a focus group study of radiation disclosure statement options for foods treated with ionizing radiation.

**DATES:** Submit written comments on the collection of information by April 9, 2001.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th Street NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

**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:**

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. The information is essential to FDA's commitment to Congress to finalize, by March 2002, any regulatory changes regarding radiation disclosure statement for foods treated with ionizing radiation. The use of normal PRA clearance procedures would not allow FDA to conduct this study within the next few months so that the results will be available to support in a timely way the ongoing policy development process.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Focus Group Study of Radiation Disclosure Statement Options for Foods Treated With Ionizing Radiation**

Under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343), FDA is mandated to ensure that labeling statements be truthful and nonmisleading. In 1986, under section 409 of the act (21 U.S.C. 348), FDA issued regulations to require that the label and labeling of retail packages or displays of foods treated with ionizing radiation include both the radura logo (the international symbol that indicates radiation treatment) and a disclosure statement (either ''Treated with radiation'' or ''Treated by irradiation'') in addition to information required by other regulations (21 CFR 179.26(c)(1) and (c)(2)). To gather information to determine if the existing requirements should be changed and how they should be changed, FDA proposes to conduct a series of six focus groups in three separate geographic locations, one of which will be in the Washington, DC area to facilitate the attendance of interested observers from FDA and industry and consumer stakeholders. The focus groups, eight to nine individuals per group, are to be held in April and May 2001. The objectives of the study are to collect information to: (1) Evaluate whether and under what conditions the current labeling requirement is an obstacle to consumer acceptance of irradiated foods, and (2) determine how other proposed versions of the disclosure statement might have different effects on consumer acceptance. The information will be used by FDA to determine if the existing requirements should be changed and how they should be changed and to fulfill FDA's commitment to Congress to finalize any regulatory changes by March 2002.

FDA estimates the burden of this collection of information as follows:

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.*

[FR Doc. 01–7678 Filed 3–28–01; 8:45 am]

**BILLING CODE 4160–01–S**

## 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