Control and Prevention (CDC) announces the following committee meeting.

*Name:* Advisory Board on Radiation and Worker Health (ABRWH).

*Time and Date:* 2 p.m.–5 p.m., March 28, 2003.

*Place:* Teleconference call will originate at the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), Atlanta, Georgia. Please see ''Supplementary Information'' for details on accessing the teleconference.

*Status:* Open to the public, teleconference access limited only by the ports available.

*Background:* The Advisory Board on Radiation and Worker Health (''the Board'') was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President, through the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a Final Rule, advice on methods of dose reconstruction which have also been promulgated as a Final Rule, evaluation of the scientific validity and quality of dose reconstructions conducted by NIOSH for qualified cancer claimants, and advice on the addition of classes of workers to the Special Exposure Cohort.

In December 2000, the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was signed on August 3, 2001, and in November 2001, the President completed the appointment of members to the Board. The initial tasks of the Board have been to review and provide advice on the proposed, interim, and final rules of HHS.

*Purpose:* This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

*Matters to be Discussed:* The agenda for this meeting will focus on the continuation of discussion and finalization of recommendations regarding the Special Exposure Cohort Notice of Proposed Rule Making.

Agenda items are subject to change as priorities dictate.

*Supplementary Information:* This conference call is scheduled for 2 p.m. Eastern Time. To access the teleconference you must dial 1–800–311–3437. To be automatically connected to the call, you will need to provide the operator with the participant code ''943833,'' and you will be connected to the call.

This meeting is being published late as the meeting date and time was not confirmed until March 14th, which did not allow the notice to be published in the **Federal Register** at least 15 days before the date of the meeting.

*Contact Person for More Information:* Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/841–4498, fax 513/458–7125.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 20, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 03–7182 Filed 3–25–03; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 03N–0084]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to FDA's electronic records and electronic signatures.

**DATES:** Submit written or electronic comments on the collection of information by May 27, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, 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.

#### Electronic Records; Electronic Signatures—21 CFR Part 11 (OMB Control No. 0910–0303)—Extension

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records; electronic signatures, and handwritten signatures executed to electronic records as

equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 11.100 | 4,500 | 1 | 4,500 | 1 | 4,500 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 11.10 | 2,500 | 1 | 2,500 | 20 | 45,000 |
| 11.30 | 2,500 | 1 | 2,500 | 20 | 45,000 |
| 11.50 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| 11.300 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| Total | | | | | 270,000 |

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

Dated: March 19, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03–7087 Filed 3–25–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 03N–0065]**

### Agency Emergency Processing Under OMB Review; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602)

**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 will permit an applicant to certify that it qualifies as a ''small business'' within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA), will help the applicant organize the information FDA needs to verify each certification, and will collect contact information to facilitate rapid resolution of any questions FDA may have concerning information the applicant has provided.

**DATES:** Fax written comments on the information collection provisions by April 25, 2003.

**ADDRESSES:** Fax written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202–395–6974, or electronically mail comments to sshapiro@omb.eop.gov. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, 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). This information is needed immediately so that the agency can decide whether an applicant is a ''small business'' within the meaning of MDUFMA. A small business is eligible for a reduced or waived fee for a medical device application or submission that is subject to a user fee under MDUFMA. If an applicant is not a small business, it must pay the standard (full) fee for any medical device application or submission it submits to FDA. FDA is requesting this emergency processing to implement 21 CFR 738(d)(2)(B) and (e)(2)(B) (§ 738(d)(2)(B) and (e)(2)(B)) of the Federal Food, Drug, and Cosmetic Act (the act); these provisions were added to the act by section 102 of MDUFMA. The use of normal clearance procedures would likely result in the prevention or disruption of this collection of information, thereby subjecting applicants who would