(CBER) and the Center for Drug Evaluation and Research (CDER). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice to request nominations for nonvoting members of industry interests on public advisory committees.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5496.

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act (FDAMA) of 1997 (21 U.S.C. 355) requires that certain newly formed FDA advisory committees include representatives from the biologics and/or drug manufacturing industries. Although not required for existing committees, the agency intends to add nonvoting industry representatives to all its CBER and CDER advisory committees.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: August 7, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–20722 Filed 8–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Registration and Listing and MDR Baseline Reporting Grassroots Meetings for Medical Device Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following two open public meetings: Registration and Listing and MDR Baseline Reporting Grassroots Meetings for Medical Device Establishments. The topics to be discussed are FDA's intention to propose changes to the current medical device registration and listing process, and Medical Device Reporting (MDR) baseline reporting process. These meetings are being conducted to provide a forum in which FDA can obtain industry views on changes to the device registration and listing system that FDA is currently considering. The changes being considered are aimed at streamlining the collection of registration and listing data, improving the accuracy and quality of the data in the system, and decreasing the time it takes establishments to register and list their devices, while ultimately reducing FDA's cost of maintaining the registration and listing system. Additional changes being considered are aimed at streamlining the collection of MDR baseline information by making this data a part of the device listing process, rather than the MDR data collection process.

DATES: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For general meeting program information: Bryan H. Benesch, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4699 ext. 122, FAX 301–594–4610, e-mail: BHB@CDRH.FDA.GOV.

For registration information about the Dallas meeting: Ms. Melissa Crabtree, Food and Drug Administration, 7920 Elmbrook Rd., suite 102, Dallas, TX 75247–4982, FAX 214–655–8114.

For registration information about the Irvine meeting: Ms. Marcia Madrigal, Pacific Region, Food and Drug Administration, 1301 Clay St., suite 1180N, Oakland, CA 94612–5217, FAX 510–637–3977.

Persons interested in attending a meeting should fax their registration to either Ms. Crabtree (Dallas) or Ms. Madrigal (Irvine), including your name and position/title, firm name, address, telephone and fax number. There is no charge to attend either meeting, but advance registration is requested due to a maximum number of 65 attendees per meeting; walk-in registrations may not be accommodated. If you need special accommodations due to a disability, please contact the appropriate person at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

Over the past 3 years, FDA has reviewed the entire registration and listing process to determine how the process can be made more efficient and accurate. This was one of many reengineering efforts conducted by the Center for Devices and Radiological Health (CDRH). This reengineering effort has resulted in a number of suggestions aimed at improving the registration and listing process for both FDA and industry. These meetings will help FDA obtain the medical device industry perspective on the changes under consideration and suggestions for additional changes. FDA has held four meetings on the same subject. These meetings took place on April 20 and 21, 1999, in California, May 25, 1999, in Rockville, MD, and on July 15, 1999, in Minneapolis, MN.

Some of the changes that FDA is currently considering include the following:

(1) Require industry submission of registration and listing information through the CDRH Internet site. What are the advantages and disadvantages to industry, and how would industry be affected if Internet based submissions are mandated?

(2) Require that parent companies register as establishments.

(3) Require that additional data elements be submitted to FDA, e.g., premarket submission numbers for those devices that have gone through the premarket notification (510(k)), humanitarian device exemption, premarket approval, or product development protocol processes.

(4) Because of the ease of submission through the CDRH Internet site, require that firms register and list within 5 days (current requirement is 30 days) of entering into an operation that requires registration and listing.

A summary report of each meeting will be available on CDRH's Internet site approximately 60 working days after each meeting. The CDRH Registration and Listing Process Reengineering Team home page may be accessed at http://www.fda.gov/cdrh/grassroots/reglist.htm.

The Office of Management and Budget (OMB) has requested FDA look at other options for the collection of the baseline data elements required by 21 CFR 803.55 of the Medical Device Reporting (MDR) regulation. This was, in part, initiated by letters from AdvaMed (formerly the Health Industry Manufacturers Association) pointing out some redundancies in information collection. Manufacturer baseline data are currently submitted to the FDA on Form 3417 and requests product information for the specific device. Some of these data elements are also collected under the Medical Device Registration and Listing regulation, 21 CFR part 807.

FDA is considering requesting some data elements found on the baseline form through an Internet site interface that will allow the device industry to register and list electronically. In an effort to eliminate duplicative reporting and provide for a more efficient data

collection process, CDRH is exploring the idea that, for MDR purposes, model level device information could also be collected as part of the proposed registration and listing process. The authority to regulate the requirements imposed upon manufacturers who submit baseline reports would remain in § 803.55.

TABLE 1.—MEETING SCHEDULES

Meeting Address	Dates	Times
Dallas Meeting, Radisson Hotel Dallas,1893 West Mockingbird Lane, Dallas, TX 75235, 214–634–8850.	Tuesday, September 19, 2000	Registration: 8 a.m. Meeting: 8:30 a.m. to 12:30 p.m.
Irvine Meeting, Food and Drug Administration, Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949–798–7714.	Wednesday, September 20, 2000	Registration: 8 a.m. Meeting: 8:30 a.m. to 12:30 p.m.

Dated: August 10, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–20718 Filed 8–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4565–N–20]

Notice of Proposed Information Collection: Comment Request; Certificate of Need (CoN) for Health Facility and Assurance of Enforcement of State Standards

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* October 16, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Building, Room 8202, Washington, D.C. 20410, telephone (202) 708–5221 this is not a toll-free number) for copies of the proposed forms and other available information.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Office of Housing Assistance and Grants Administration, Participation Division, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone number (202) 708–3000 (this is not a foll-free number) for copies of the proposed forms and other available.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Certificate of Need (CoN) for Health Facility and Assurance of Enforcement of State Standards.

OMB Control Number, if applicable: 2502–0201.

Description of the need for the information and proposed use: This Notice requests an extension of the use of Form HUD–2576–HF, Certificate of Need for Health Facility and Assurance of Enforcement of State Standards, as authorized by Sections 232, 242 of the National Housing Act. These certifications are prepared by the State Agencies designated in accordance with Section 604(a)(1) or Section 1521 of the Public Health Service Act. Sections 232 and 242 require State certification that there is a need for the facility, that there are minimum standards of licensing and for operating the project, and that the standards will be enforced for the insured project.

Agency form numbers, if applicable: HUD–2576–HF.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of responses, and hours of response: The number of respondents is 50; the frequency of responses is 1 per year; estimated time to prepare form is approximately 12 minutes (.20 hour), and the estimated total annual burden hours are 10.

Status of the proposed information collection: Reinstatement with change.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: August 10, 2000.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 00–20805 Filed 8–15–00; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4565–N–19]

Notice of Proposed Information Collection: Comment Request; Previous Participation Certification

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date*: October 16, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB