of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

5. Antiviral Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections.

6. Arthritis Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.

7. Cardiovascular and Renal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders.

8. Dermatologic and Ophthalmic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

9. Drug Abuse Advisory Committee

Advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances and recommends actions to be taken by the Food and Drug Administration with regard to marketing, investigation, and control of such drugs or other substances.

10. Endocrinologic and Metabolic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

11. Gastrointestinal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal disorders.

12. Medical Imaging Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

13. Nonprescription Drugs Advisory Committee [1]

Reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

14. Oncologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer.

15. Peripheral and Central Nervous System Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic disease.

16. Pharmacy Compounding Advisory Committee [1]

Provides advice on scientific, technical, and medical issues concerning drug compounding by licensed practitioners.

17. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

18. Pulmonary-Allergy Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

II. Nomination Procedure

Any organization in the biologics and/or drug manufacturing industry wishing to participate in the selection of an appropriate industry representative of a particular advisory committee identified above, may nominate one or more qualified persons. Persons who nominate themselves as representatives of industry interests for a certain advisory committee may not participate in the overall selection process.

Nominees should be full-time employees of firms that manufacture products regulated by the agency or of consulting firms that represent biologics and/or drug manufacturers. Nomination packages should include a cover letter indicating the committee of interest and complete curriculum vitae of each nominee. The term of office is up to 4 years.

III. Selection Procedure

A letter will be sent to each party that has sent a nomination package to FDA for a particular advisory committee. The letter will provide the complete list of all nominees. It is the responsibility of each nominating organization to consult with one another to select a single member to represent the industry interests for the respective advisory committee. This must be completed within 60 calendar days upon receipt of the letter. If no individual is selected within the 60 calendar days, the Commissioner of Food and Drugs will select a nonvoting member to represent the industry interests for the respective advisory committee.

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. 00–20721 Filed 8–15–00; 8:45 am]

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[1] Currently, there is a standing representative of industry interests on this advisory committee.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Industry Representation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention of adding one nonvoting representative of industry interests to the membership of its existing advisory committees that do not already have such nonvoting industry representation under the purview of the Center for Biologics Evaluation and Research

(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