such approach satisfies the applicable statute, regulations, or both.

II. Comments

Interested persons may, on or before October 30, 1997, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

In order to receive the ''Medical Device Labeling—Suggested Form and Content'' draft guidance via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 119 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (www). CDRH maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH homepage includes the ''Medical Device Labeling—Suggested Form and Content'' draft guidance, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH homepage may be accessed at ''http://www.fda.gov/cdrh''. The ''Medical Device Labeling—Suggested Form and Content'' draft guidance is available at ''http://www.fda.gov/cdrh/draftgui.html''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. Select menu choice 1–FDA Bulletin Board Service. At login prompt type ''bbs'' and hit Enter, at password prompt type ''bbs'' and hit Enter, at this screen, hit Enter (brings you to FDA Home Page), using tab key, select Medical Devices/Radiological Health—hit Enter, using
tab key, select Topic Index—hit Enter, using tab key, select ''L''—hit Enter, under ''Labeling'' is the title of the draft guidance ''Medical Device Labeling-Suggested Form and Content''—select text file—hit Enter, use space bar to move page to page, in order to view the whole document.

Dated: July 2, 1997.

Joseph A. Levitt.

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

[FR Doc. 97–20313 Filed 07–31–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0312]

Medical Devices; Device Labeling Requirements; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an open public meeting to discuss the draft guidance entitled ''Medical Device Labeling—Suggested Format and Content,'' which is being announced elsewhere in the issue of the **Federal Register**, and to identify other concerns that manufacturers and others may have regarding the medical device labeling regulation or the labeling procedures used by the Center for Devices and Radiological Health (CDRH). Revision of the labeling requirements for in vitro diagnostic products is not being considered at this time. Health care practitioners and lay users of medical devices are encouraged to participate in the public meeting.

DATES: The public meeting will be held on September 5, 1997, from 9 a.m. to 5 p.m. Written notices of participation should be filed by August 22, 1997. Submit written comments by September 24, 1997.

ADDRESSES: The public meeting will be held at the Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Submit written notices of participation and written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia A. Kingsley, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2436, or via Internet at ''PAK@cdrh.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

The labeling of most medical devices is regulated by part 801 (21 CFR part 801). Since the original Medical Device Amendments of 1976, the agency has issued a number of guidance documents to assist applicants in developing effective and informative medical device labeling. These documents include the General Program Memorandum #G91–1, entitled ''Device Labeling Guidance,'' as well as numerous device-specific documents. Over time, the agency has received feedback that manufacturers have some concerns with part 801 and other agency procedures concerning device labeling. In addition, the agency has heard from users of devices that medical device labeling is less useful than it might be. These comments have encouraged the agency to reevaluate its labeling regulations and guidance.

Concerns about the effectiveness of communication through labeling of FDA regulated products extend beyond medical devices. Research on label content and format preferences in the user community has been conducted and a public hearing has been held by the Center for Drug Evaluation and Research. The results of the research are available in the transcript of the public hearing in Docket No. 95N–0314. CDRH conducted research with health care practitioners to determine how they use device labeling and what would make it more useful to them. The report entitled ''Draft Initial Report on Medical Device Labeling: Health Care Practitioners' Medical Device Information and Labeling Needs—Results of Qualitative Research'' is available via the internet on CDRH's homepage at ''http://www.fda.gov/cdrh/humfac/hufacact.html#Draft Initial Report''. The results of the research were used in the development of the draft guidance entitled ''Medical Device Labeling—Suggested Format and Content,'' which was placed on the FDA homepage in April 1997, and is being announced elsewhere in this issue of the **Federal Register**.

The agency notes that labeling of in vitro diagnostic products are regulated under 21 CFR 809.10 and are not subject to the draft guidance, nor will they be the subject of discussion at the September 5, 1997, public meeting.

II. Medical Device Labeling Issues

FDA is soliciting comments on the notice of availability, which is published elsewhere in this issue of the **Federal Register**. The draft guidance which was previously posted on FDA's homepage also solicited comments. The agency also wants to gather information on broader regulatory and procedural issues regarding labeling that may be important to manufacturers, users, and FDA. For that reason, the agency is holding a public meeting to discuss issues raised by the suggestions in the draft guidance, the present labeling regulation in part 801, and any other concerns that manufacturers and the user community may have with medical device labeling.

The agency is particularly interested in responses to the following questions:

1. For which types of devices would labeling consistent with the draft guidance be inappropriate? Why would it be inappropriate?

2. Should there be different labeling requirements for different types of medical devices?

3. What are specific labeling requirements for over-the-counter devices?

4. Are there other types of devices that should have labeling format and content requirements that are different from those discussed in the draft guidance?

5. The draft guidance recommended the development of a summary document called the Essential Prescribing Information (EPI) label. Are there any devices for which such a piece or section of labeling might not be applicable? Why not?

6. What are the benefits to industry and/or the user community of adopting the content and format discussed in the draft labeling guidance?

7. What costs would be incurred by industry for adopting a consistent format design and highlight information? What are the costs of making the labeling change? What factors significantly affect labeling costs? How frequently is device labeling revised? What strategies can be used to lessen the cost to industry?

8. Should CDRH implement consistent format and content and the EPI as requirements for medical device labeling?

9. Are there recommendations in the guidance that create new impediments to developing labeling for the international marketplace? Are there ways that CDRH could facilitate harmonization efforts in device labeling? Should provisions be made for the use of symbols in device labeling?

10. What methods are available to provide users with more access to device labeling?

11. Are there other issues with the labeling regulation or the labeling procedures used by CDRH that the agency should address?

12. Relating to FDA's medical device reporting system, what are the concerns if the agency would require manufacturers to submit periodic summary reports for common and anticipated adverse events that are listed in the device labeling, in lieu of individual incident reports. The agency's interest in requiring summary reporting for anticipated adverse events already listed in the labeling is to improve the signals received in the medical device reporting system and to reduce repeat reports of known problems when further agency action is unlikely. What adverse events should still be reported individually, even if the events are anticipated and listed in the labeling?

Interested persons who wish to participate may, on or before August 22, 1997, submit notice of participation to the Dockets Management Branch (address above). All notices of participation submitted should be identified with the docket number found in brackets in the heading of this document and should contain the name, address, telephone number, business affiliation of the person requesting to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation.

Individuals or groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. FDA will allocate the time available for the meeting among the persons who properly file a notice of appearance.

Persons who are unable to participate on the day of the meeting are encouraged to submit written comments to the Dockets Management 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20312 Filed 7-31-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental Research; Notice of Closed Meeting

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 National Institute of Dental Research Special Emphasis Panel (SEP) meeting:

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of R01s & R29 (97–43).

Date: August 12, 1997.

Time: 9:30 a.m.

Place: Natcher Building, Rm. 4AN–44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN–44F, Bethesda, MD 20892, (301) 594–2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

This notice is being published less than fifteen days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research)

Dated: July 29, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–20324 Filed 7–31–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Notice is hereby given of a meeting of the NIDCD Work Group on Peer Review on August 21–23, 1997 in Conference Room 10, Building 31, the National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892. The meeting will be held to discuss issues involving the initial review of grant applications and will be held from 3 to 5 p.m. on August 21, 8:30 a.m. to 5 p.m. on August 22, and from 8:30 a.m. to 12 p.m. on August 23.

The entire meeting is open to the public. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Craig A. Jordan, Ph.D., Division of Extramural Activities, NIDCD, EPS Room 400C, Bethesda, MD 20892, 301–496–8693 in advance of the meeting.

Dated: July 29, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–20325 Filed 7–31–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting of National Advisory Environmental Health Sciences Council

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Environmental Health Sciences Council, September 15–16, 1997, Building 101 Conference Room, South Campus, Research Triangle Park, North Carolina.

This meeting will be open to the public from 9:00 a.m. to approximately 3:45 p.m. on September 15 for the report of the Director, NIEHS, and for discussion of the NIEHS budget, program policies and issues, recent legislation, and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public from approximately 3:45 p.m. on September 15 to adjournment on September 16, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dr. Anne Sassaman, Director, Division of Extramural Research and Training,