information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Science Board to the Food and Drug Administration

Date, time, and place. June 13, 1996, 8:30 a.m., Sheraton—Crystal City, Ballroom A, 1800 Jefferson Davis Hwy., Arlington, VA.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; Susan Homire, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Board to the Food and Drug Administration, code 12603. Please call the hotline for information concerning any possible changes.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor, and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations must notify the contact person before June 6, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

Open board discussion. The board will continue its discussions related to FDA's approach to toxicity, carcinogenicity and biomaterials testing.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: May 20, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–13105 Filed 5–23–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory

committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. June 11, 1996, 8:30 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Marriott Courtyard Hotel, 2500 Research Blvd., Rockville, MD. Attendees requiring overnight accommodations may contact the hotel at 301–670–6700 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should notify the contact person listed below. The availability of special accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:45 a.m., unless public participation does not last that long; open committee discussion, 9:45 a.m. to 4 p.m.; closed committee deliberations, 4 p.m. to 5 p.m.; Marilyn N. Flack, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ear, Nose, and Throat Devices Panel, code 12522. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before May 29, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss a premarket approval application that seeks to substantiate the safety and effectiveness of a bronchoscope device utilizing autofluorescence to aid in detection of abnormal lung tissue.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Oncologic Drugs Advisory Committee

Date, time, and place. June 13 and 14, 1996, 8:30 a.m., Holiday Inn—Gaithersburg, Walker and Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, June 13, 1996, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; open committee discussion, June 14, 1996, 8:30 a.m. to 1 p.m.; closed committee deliberations, 1 p.m. to 3:30 p.m.; Jannette O'Neill-Gonzalez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before June 7, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On June 13, 1996, the committee will discuss: (1) New drug application (NDA) 20–571 Camptosar™ (irinotecan hydrochloride injection, The Upjohn Co.), indicated for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5–FU-based therapy; and (2) NDA 20–036/S–011 Aredia® (pamidronate disodium for injection, Ciba-Geigy Corp.), indicated for use in conjunction with standard antineoplastic therapy for treatment of osteolytic bone metastases. On the morning of June 14, 1996, the committee will discuss NDA 20–637, Gliadel Wafer® (polifeprosan 20 with carmustine, Guilford Pharmaceuticals), indicated for use as an adjunct to surgery to prolong survival in patients with a malignant glioma.

Closed committee deliberations. On the afternoon of June 14, 1996, the committee will review trade secret and/or confidential commercial information relevant to pending investigational new drug applications and NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Blood Products Advisory Committee

Date, time, and place. June 20 and 21, 1996, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms II and III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, June 20, 1996, 8 a.m. to 11 a.m.; open public hearing, 11 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 3:30 p.m.; open public hearing, 3:30 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 5:30 p.m.; open committee discussion, June 21, 1996, 8 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3 p.m., unless public participation does not last that long; open committee discussion, 3 p.m. to 4 p.m.; Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Blood Products Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before June 14, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On the morning of June 20, 1996, updates on relevant public health issues will be presented and an overview of draft reviewer guidance for blood establishment computer software will be presented and discussed. In the afternoon, there will be discussion of use of hemoglobin solutions in fluid rescuscitation from hemorrhagic shock; in particular, issues in clinical trials. On the morning of June 21, 1996, proposed revisions to the human immunodeficiency virus (HIV) re-entry algorithm will be reviewed and discussed. In the afternoon, the Calypte Laboratories test for anti-HIV in urine will be presented and discussed.

Closed committee deliberations. On June 20, 1996, the committee will review trade secret and/or confidential commercial information relevant to current or pending products. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: May 20, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–13177 Filed 5–23–96; 8:45 am]

BILLING CODE 4160–01–F

Compressed Medical Gas Industry; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Office of the Southeast Region, and the Center for Drug Evaluation and Research) is announcing a free public workshop on FDA regulatory requirements for the compressed medical gas industry. The workshop is designed to assist the industry in complying with regulations for manufacturing and repacking medical gases.

DATES: The public workshop will be held on Tuesday, June 4, 1996, from 8:30 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at the Rural Development Center, UGA Cooperative Extension Service, U.S. 41 North and I–75 (exit 21), Tifton, GA.

FOR FURTHER INFORMATION CONTACT: Douglas B. Brogden or Jackie M. Douglas, FDA Atlanta District Office, 225 Tift Ave., rm. 107, Tifton, GA 31794, 912–382–5963, FAX 912–386–9610. Those persons interested in attending this meeting should FAX their registration including name(s), firm name, address, telephone and FAX numbers, and any specific questions about the workshop to Douglas B. Brogden or Jackie M. Douglas (address above) by May 15, 1996. There is no registration fee for this workshop. Advance registration is required. Space is limited and all interested parties are encouraged to register early.

SUPPLEMENTARY INFORMATION: FDA's survey of the medical gas industry shows that many medical gas firms are either unaware of applicable regulations and guidelines or not in compliance with applicable requirements. This workshop is designed to assist the medical gas industry in complying with regulations for manufacturing and repacking medical gases. This workshop is free of charge to attendees.

Dated: May 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13104 Filed 5–23–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0133]

Guidance for Industry; The Content and Format for Pediatric Use Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Industry; The Content and Format for Pediatric Use Supplements.'' This guidance was prepared by the Pediatric Subcommittee of the Medical Policy Coordinating Committee (MPCC) of the Center for Drug Evaluation and Research (CDER) in collaboration with the Center for Biologics Evaluation and Research (CBER). The availability of this document is intended to provide guidance on the format and content of ''pediatric use'' labeling supplements to approved applications for drugs and licensed biological products. This labeling information is intended to provide practitioners with sufficient ''pediatric use'' information upon which to base a decision to prescribe a drug for use in pediatric patients.

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry; The Content and Format For Pediatric Use Supplements'' to the Division of Communications Management, Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855 or to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to the INTERNET may request that the guidance document be sent by ''bounce back e-mail'' using the following address: GDEPED@a1.CBER.FDA.GOV. The guidance document may also be obtained through the INTERNET via File Transfer Protocol (FTP). Requesters should connect to the CDER FTP server at ''CDVS2.CDER.FDA.GOV'' and change to the ''guidance'' directory. The ''READ.ME'' file in that subdirectory describes the available documents that may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. Further, the guidance document is available via the World Wide Web (WWW) and Gopher. To obtain the guidance document via the WWW requesters should connect to the FDA home page at ''WWW.FDA.GOV'' and go to the CDER ''Human Drugs'' icon. To obtain the guidance document via Gopher requesters should connect to CDER's Gopher server at ''GOPHER.CDER.FDA.GOV'' and select the ''Industry Guidance'' menu option. Finally, the guidance document is available via FAX by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709.

Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding human drugs: Terry Martin, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–5460.

Regarding biological products: Elaine Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0641.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance entitled ''Guidance for Industry; The Content and Format For Pediatric Use Supplements.'' The guidance is intended to provide sponsors with format and content information for submitting ''pediatric use'' labeling supplements to approved applications for drugs or licensed biological products. The guidance provides a general description of the information that should be submitted in a ''pediatric use'' supplement, including draft revised labeling and a marked-up copy of the current labeling, clearly showing all revisions; the appropriate paragraph of § 201.57(f)(9) (21 CFR 201.57(f)(9)) that applies and a justification for the paragraph; a basis for concluding that the course of the disease and the effects of the drug are similar in the pediatric and adult population if changes in labeling fall under § 201.57(f)(9)(iv); the age categories for which pediatric data are being submitted; identification of the kind of pediatric data submitted within