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]

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[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