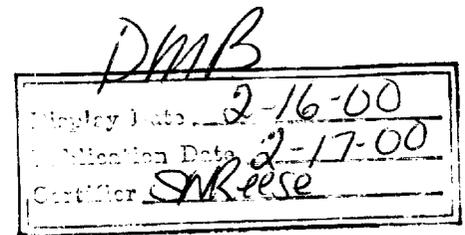


DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

**Food and Drug Administration/Industry Exchange Workshop on Fresh Air 2000—
Medical Gas Requirements; Public Satellite Broadcast Workshop**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Center for Drug Evaluation and Research, Office of Regulatory Affairs, and the Regional Small Business Assistance Offices is announcing a satellite broadcast workshop on FDA medical gas requirements. Through the workshop, FDA seeks to help ensure that the medical gas community understands existing FDA requirements for manufacturing, labeling, and distribution of medical gases and takes appropriate actions to establish effective manufacturing controls, thus preventing regulatory problems when inspections occur.

Date and Time: See Table 1 following the *Location* section of this document.

Location: See Table 1 below.

TABLE 1

Workshop Address	Date and Local Time	Registrar
SAN JUAN, FDA San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901.	Wednesday, March 15, 2000 2 p.m. to 6 p.m. Atlantic time	Daniel Gonzalez, FDA San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901, 787-729-6894, FAX: 787-729-6658, e-mail: dgonzale@ora.fda.gov.
AUGUSTA, Maine Department of Agriculture, Agricultural Bldg., 333 Cony Rd., Augusta, ME 04330.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Becky Maxim, FDA, Capital West Business Center, 81 Leighton Rd., suite 14, Augusta, ME 04330-9303, 207-622-8268, ext. 13, FAX: 207-622-8273, e-mail: rmaxim@ora.fda.gov
WINCHESTER, FDA/Winchester Engineering and Analytical Center, 109 Holton St., Winchester, MA 01890.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Herman B. Janiger, FDA Northeast Region, 158-15 Liberty Ave., Jamaica, NY 11433-1034, 718-662-5618, FAX: 718-662-5434, e-mail: hjaniger@ora.fda.gov.
NEW YORK CITY/JAMAICA, NY, FDA Northeast Regional Office, 158-15 Liberty Ave., Jamaica, NY 11433-1034.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Herman B. Janiger, FDA Northeast Region, 158-15 Liberty Ave., Jamaica, NY 11433-1034, 718-662-5618, FAX: 718-662-5434, e-mail: hjaniger@ora.fda.gov.

TABLE 1—Continued

Workshop Address	Date and Local Time	Registrar
PHILADELPHIA, FDA Philadelphia District Office, 2d and Chestnut Sts., rm. 900, U.S. Customhouse, Philadelphia, PA 19106.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Anitra Brown-Reed, FDA Philadelphia District, 2d and Chestnut Sts., rm. 900, U.S. Customhouse, Philadelphia, PA 19106, 215-597-4390, ext. 4548, FAX: 215-597-4660, e-mail: abrown2@ora.fda.gov.
BALTIMORE, FDA Baltimore District Office, 900 Madison Ave., Baltimore, MD 21201.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Valerie Matthews, FDA Baltimore District, 900 Madison Ave., Baltimore, MD 21201, 410-962-3396, ext. 111, FAX: 410-962-0044, e-mail: vmatthe1@ora.fda.gov.
ROCKVILLE, FDA, Parklawn Conference Center, 5600 Fishers Lane, 3d floor, rms. G and H, Rockville, MD 20857.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Erik Henrikson, FDA Center for Drug Evaluation and Research (HFD-320), 7520 Standish Pl., Rockville, MD 20855, 301-827-0072, FAX: 301-594-2202, e-mail: henriksone@cder.fda.gov.
CINCINNATI, FDA Cincinnati District Office, 6751 Steger Dr., Cincinnati, OH 45237.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Mary Jane Jeffries, FDA Cincinnati District, 6751 Steger Dr., Cincinnati OH 45237, 513-679-2700, ext. 115, FAX: 513-679-2771, e-mail: mjeffrie@ora.fda.gov.
MAITLAND, FDA Florida District Office, 555 Winderly Pl., suite 200, Maitland, FL 32751.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Frank Goodwin, FDA Florida District Office, 555 Winderly Pl., suite 200, Maitland, FL 32751, 407-475-4707, FAX: 407-475-4768, e-mail: fgoodwin@fda.ora.gov.
ATLANTA, FDA Atlanta District Office, 60 8th St. NE., Atlanta, GA 30309.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Teresa Thompson, FDA, 2302 West Meadowview Rd., suite 203, Greensboro, NC 27407, 336-333-5419, FAX: 336-333-5563, e-mail: tthomps@ora.fda.gov.
DETROIT, FDA District Office, 1560 East Jefferson Ave., Detroit, MI 48207 (attendance limited to one person per company).	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Eastern time	Evelyn DeNike, FDA Detroit District, 1560 East Jefferson Ave., Detroit, MI 48207-3179, 313-226-6260, ext. 149, FAX: 313-226-3076, e-mail: edenike@ora.fda.gov.
NASHVILLE, FDA Nashville Branch, 297 Plus Park Blvd., Nashville, TN 37217.	Wednesday, March 15, 2000 1 p.m. to 5 p.m. Central time	Kari Norton, FDA Nashville Branch, 297 Plus Park Blvd., Nashville, TN 37217, 615-781-5388, ext. 112, FAX: 615-781-5383, e-mail: knorton@ora.fda.gov.
CHICAGO, FDA Chicago District Office, 300 South Riverside Plaza, suite 550 South Chicago, IL 60606.	Wednesday, March 15, 2000 12 m. to 4 p.m. Central time	Patricia Lewis, FDA Chicago District, 300 South Riverside Plaza, suite 550 South Chicago, IL 60606, 312-353-7379, FAX: 312-886-3280, e-mail: plewis@ora.fda.gov.
MINNEAPOLIS/ST. PAUL, Fort Snelling, 1 Federal Dr., rm. 196, Fort Snelling, MN 55111.	Wednesday, March 15, 2000 12 m. to 4 p.m. Central time	Carrie Hoffman, FDA Minneapolis District, 240 Hennepin Ave., Minneapolis, MN 55401, 612-334-4100, ext. 159, FAX: 612-334-4142, e-mail: choffman@ora.fda.gov.
LENEXA, FDA Kansas City District Office, 11630 West 80th St., P.O. Box 15905, Lenexa, KS 66285-5905.	Wednesday, March 15, 2000 12 m. to 4 p.m. Central time	Tywanna Paul, FDA Kansas City District, 11630 West 80th St., Lenexa, KS 66285-5905, 913-752-2141, FAX: 913-752-2111, e-mail: tpaul@ora.fda.gov.
NEW ORLEANS, FDA New Orleans District Office, 6600 Plaza Dr., suite 400, New Orleans, LA 70127.	Wednesday, March 15, 2000 12 m. to 4 p.m. Central time	Kari Norton, FDA Nashville Branch, 297 Plus Park Blvd., Nashville, TN 37217, 615-781-5388, ext. 112, FAX: 615-781-5383, e-mail: Knorton@ora.fda.gov.
DENVER, FDA Denver District, Denver Federal Center, Bldg. 20, 6th and Kipling Sts., Denver, CO 80225-0087.	Wednesday, March 15, 2000 11 a.m. to 3 p.m. Mountain time	Virlie Walker, FDA Denver District, Federal Center, Bldg. 20, 6th and Kipling Sts., Denver, CO 80225-0087, 303-236-3018, FAX: 303-236-3551, e-mail: vwwalker@ora.fda.gov.

TABLE 1—Continued

Workshop Address	Date and Local Time	Registrar
DOWNEY, The Gas Company, Energy Resource Center, 9240 East Firestone Blvd., Downey, CA 90241.	Wednesday, March 15, 2000 10 a.m. to 2 p.m. Pacific time	Virgilio Pacio, FDA, 4510 Executive Dr., suite 225, San Diego, CA 92121, 858-550-3850, ext. 116, FAX: 858-550-3860, e-mail: vpacio@ora.fda.gov.
BOTHELL, FDA Seattle District Office, 22201 23d Dr. SE., Bothell, WA 98021-4421.	Wednesday, March 15, 2000 10 a.m. to 2 p.m. Pacific time	Connie Rezendes, FDA Seattle District, 22201 23d Dr. SE., Bothell, WA 98021-4421, 425-402-3178, FAX: 425-483-4996, e-mail: crezende@ora.fda.gov.
ALAMEDA, FDA San Francisco District Office, 1431 Harbor Bay Pkwy., Alameda, CA 94502.	Wednesday, March 15, 2000 10 a.m. to 2 p.m. Pacific time	Steven Gillenwater, FDA San Francisco District, 1431 Harbor Bay Pkwy., Alameda, CA 94502, 510-337-6802, FAX: 510-337-6702, e-mail: sgillenw@ora.fda.gov.

Contact: Erik N. Henrikson, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-827-0072, or e-mail henriksons@cder.fda.gov.

Registration: Send registration information, as listed in Table 1 of this document, to the registrar for the site you wish to attend. Space is limited, therefore interested parties are encouraged to register early. The workshop is free of charge and open to the public, either through direct down-linking of the program or through attendance at one of the public meeting sites listed in Table 1 of this document. If you need special accommodations due to a disability, please inform the registrar for your site at least 7 days in advance of the workshop. Those who will be down-linking the program to their own locations and who will not attend one of FDA's public sites do not need register with FDA in advance.

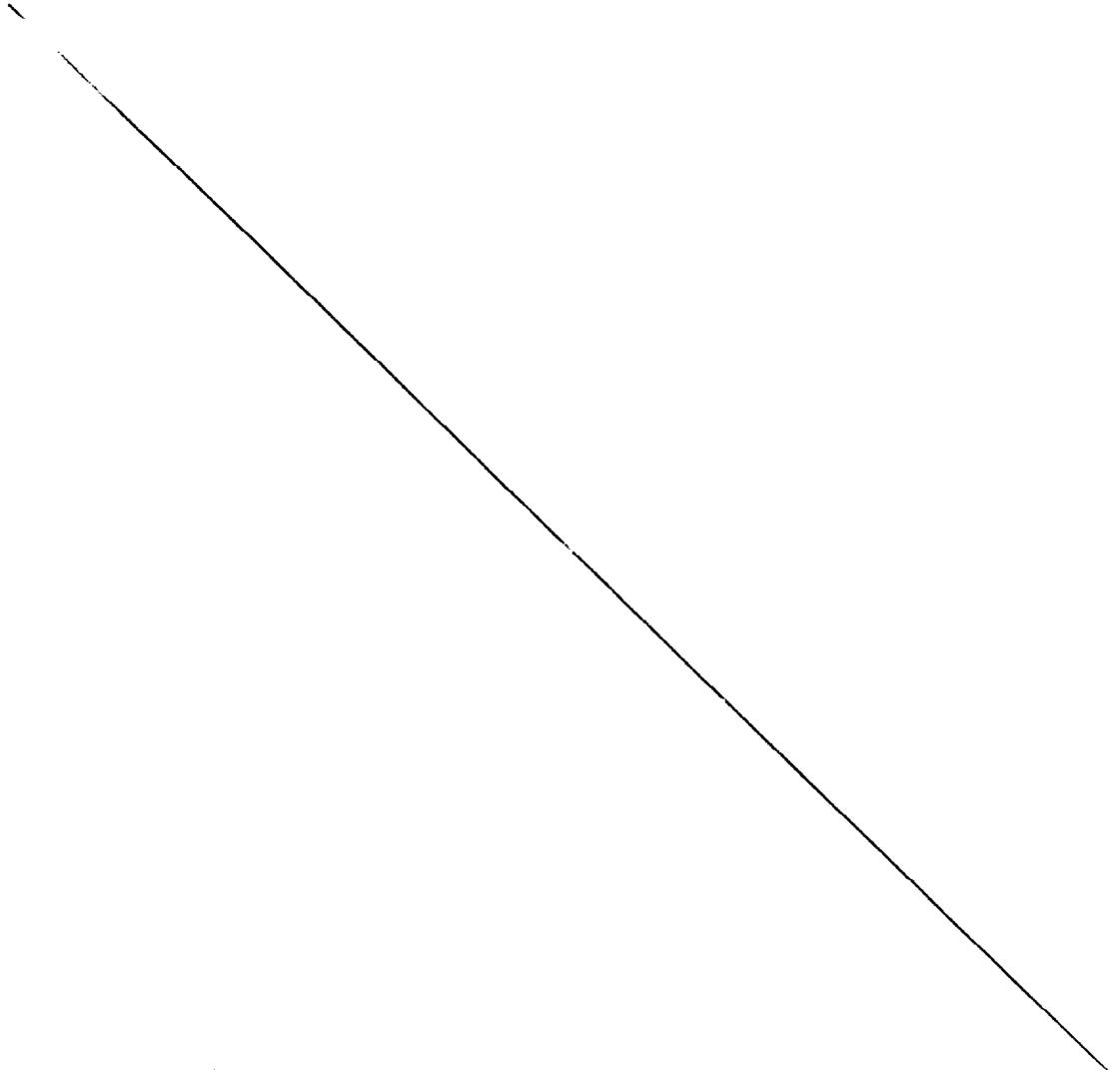
Additional meeting sites are available on the Internet at <http://www.fda.gov/cder/workshop.htm>.

The broadcast is also available for down-linking, free of charge, to anyone with a steerable satellite dish capable of accessing c-band broadcast signals. Satellite coordinates and technical information will be posted on the Internet at <http://www.fda.gov/cder/workshop.htm>. Coordinates will not be available until 2 to 3 weeks prior to broadcast. Questions regarding satellite down-linking prior to day of broadcast should be directed to the Satellite Voicemail Line at 301-594-2263.

The workshop scheduled above will help implement the FDA Plan for Statutory Compliance (developed under section 406 of the FDA Modernization Act (21 U.S.C. 393)) through working more closely with stakeholders and ensuring access to needed scientific and technical expertise. This workshop also complies with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) that requires outreach activities by Government agencies directed to small businesses.

The meeting announcement and registration form may also be accessed on the Internet at <http://www.fda.gov/cder/workshop.htm>.

The following information is requested for registration:



REGISTRATION FORM

Fresh Air 2000—Medical Gas Workshop

Instructions: To register, complete this form and mail or fax it to the Registrar by March 8, 2000, for the workshop you wish to attend.

Location: _____

Name of attendee: _____

Title: _____

Company: _____

Address: _____

Is your company a small business of less than 500 employees? Yes _____ No _____

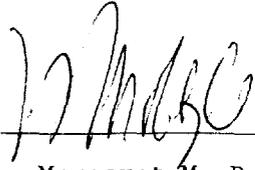
Telephone: _____

FAX: _____

E-mail: _____

Dated: 2/8/00

February 8, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

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