

**ADDRESSES:** Submit written or electronic requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Lawrence J. Lesko, Center for Drug Evaluation and Research (HFD-850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5690, or

David Green, Center for Biologics Evaluation and Research (HFM-579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5349.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications." This guidance provides recommendations on the use of exposure-response information in the development of drugs, including therapeutic biologics. The guidance describes: (1) The uses of exposure-response studies in regulatory decisionmaking; (2) the important considerations in exposure-response study designs to ensure valid information; (3) the strategy for prospective planning and data analyses in the exposure-response modeling process; (4) the integration of assessment of exposure-response relationships into all phases of drug development; and (5) the format and content of reports of exposure-response studies.

In the **Federal Register** of April 2, 2002 (67 FR 15576), FDA announced the availability of a draft guidance for industry. The April 2002 document gave

interested persons an opportunity to submit comments through June 3, 2002. The agency received 12 comments on the draft guidance. All comments received during the comment period have been carefully reviewed and changes were made to this guidance, where appropriate.

This guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). This guidance represents the agency's current thinking on study design, data analysis, and regulatory applications of exposure-response relationships. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: April 29, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 03D-0165]**

**Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for

industry entitled "Current Good Manufacturing Practice for Medical Gases." This draft guidance discusses how the requirements in Title 21, Code of Federal Regulations, parts 210 and 211, current good manufacturing practice (CGMP) regulations apply to medical gases. Medical gases are subject to these regulations because they are considered prescription drugs.

**DATES:** Submit written or electronic comments on the draft guidance by September 3, 2003. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance for industry to the Office of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Duane S. Sylvia, Center for Drug Evaluation and Research (HFD-325), Food and Drug Administration, 7520 Standish Pl., suite 272, Rockville, MD 20855, 301-594-0095 x 8, [SylviaD@cder.fda.gov](mailto:SylviaD@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This guidance is intended to provide recommendations on how to comply with CGMPs for manufacturing, filling, transfilling, cascading, and transferring compressed and cryogenic medical gases. The guidance should help manufacturers and distributors comply with the CGMP requirements to ensure the identity, strength, quality, and purity of medical gases.

FDA's first guidance on compressed medical gases was issued in June of 1981 and revised in 1983. In February of 1989, FDA issued a revised guidance to address issues related to the home care area, including the delivery of oxygen to patients at home. Once finalized, this guidance will supersede those earlier versions. The guidance has been updated to reflect CGMPs in FDA's regulations, 21 CFR parts 210 and 211.

This level 1 draft guidance is being issued consistent with FDA's good guidance practice regulations (21 CFR