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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

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Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Current Good Manufacturing Practice for Medical Gases." This draft guidance discusses how the requirements in Title 21, Code of Federal Regulations, parts 210 and 211, current good manufacturing practice (CGMP) regulations apply to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DATES: Submit written or electronic comments on the draft guidance by [*insert date 120 days after date of publication in the* **Federal Register**]. 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ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Office of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville,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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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

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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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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.

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 10.115). The draft guidance, when finalized, will represent the agency's current thinking on CGMPs for medical gases. 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 regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two paper copies of any written comments, 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. Received comments may be seen 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/ohrms/dockets/default.htm, and http://www.fda.gov/cder/dmpq/gases.htm.

Dated: 4/29/03
April 29, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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