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In the **Federal Register** of April 2, 2002 (67 FR 15576), FDA announced the availability of a draft guidance for industry.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 The agency received 12 comments on the draft guidance.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.

[FR Doc. 03–11074 Filed 5–5–03; 8:45 am]

BILLING CODE 4160–01–S

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.

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: April 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11073 Filed 5–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2003 Application Cycle for the Nursing Scholarship Program 93.908

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Nursing Scholarship Program for Fiscal Year 2003.

Authorizing Legislation: These applications are solicited under section 846(d) of the Public Health Service (PHS) Act, as amended by Pub. L. 107–205.

Purpose of Award: The Nursing Scholarship Program (NSP) provides scholarships to individuals for attendance at schools of nursing. In exchange, the scholarship recipients agree to serve for a period of not less than 2 years at a health care facility with a critical shortage of nurses.

Eligible Applicants: An ''eligible applicant'' is a U.S. citizen or national who is enrolled or accepted for enrollment in a professional program as a full-time or part-time student in an accredited school of nursing.

A ''school of nursing'' is a collegiate, associate degree or diploma school of nursing in a State.

Statutory Matching or Cost Sharing Requirement: None.

Funding Preferences: Section 846(e) of the PHS Act provides that a funding preference shall be given to qualified applicants with the greatest financial need. To evaluate financial need, the HRSA will use the Department of Education's Expected Family Contribution (EFC) determination. The EFC measures a student's family's financial strength and is used to determine eligibility for federal student aid.

The following funding preferences will apply in Fiscal Year 2003:

(a) First funding preference will be given to qualified applicants who have a zero EFC, have agreed to complete their nursing program as a full-time student, and are enrolled or accepted for enrollment in an undergraduate nursing program;

(b) Second funding preference will be given to the remaining qualified applicants who have a zero EFC;

(c) Third, qualified applicants who have an EFC that exceeds zero will be grouped according to their EFC in increments of $500 from highest to lowest need (*i.e.*, applicants with EFC of $1–$500, applicants with EFC of $501–$1,000, etc.), and these groups will be funded, to the extent monies remain available, in order of decreasing need. Within each group, applicants who have agreed to complete their nursing program as a full-time student and are enrolled or accepted for enrollment in an undergraduate nursing program will be funded first, then the remaining qualified applicants within that group will be funded.

If there are insufficient funds to award a contract to all qualified applicants who meet a given funding preference, applicants will be randomly selected within that preference level until all funds are expended.

Estimated Amount of Available Funds: $3,800,000.

Estimated Number of Awards: 76.

Service Requirement: In exchange for an NSP scholarship, a participant agrees to provide full-time clinical service for not less than 2 years at a health care facility with a critical shortage of nurses. Under certain circumstances, an individual may complete his or her service obligation on a part-time basis.

Pursuant to section 801(11) of the PHS Act, a ''health care facility'' includes the following: (A) An Indian Health Service Health Center, (B) a Native Hawaiian Health Center, (C) a Hospital, (D) a Federally Qualified Health Center, (E) a Rural Health Clinic, (F) a Nursing Home, (G) a Home Health Agency, (H) a Hospice Program, (I) a State or Local Public Health Department including a Public Health Clinic within these Departments, (J) a Skilled Nursing Facility and (K) an Ambulatory Surgical Center. Each year, HRSA will determine which health care facilities with a critical shortage of nurses have the highest need. NSP participants will only be allowed to fulfill their service obligation at those health care facilities with a critical shortage of nurses which have been identified by the HRSA as having the highest priority need.

Application Request and Award Process: Application materials are expected to be available on May 16, 2003. Individuals may only request additional application information by calling 1–866–867–6856. In order to be considered for this scholarship, completed applications must be received, or postmarked, on or before, June 30, 2003. Applications received and postmarked after the deadline will not be considered. Awards will be made no later than September 30, 2003.

FOR FURTHER INFORMATION CONTACT: CAPT. Bruce Baggett, Division of National Health Service Corps, Bureau of Health Professions, HRSA, Room 8A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Central telephone is 1–800–435–6464; e-mail *bbaggett@hrsa.gov;* Fax number is (301) 594–4981.

Paperwork Reduction Act: The application for the NSP has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0915–0146.

The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR Part 100). This program is also not subject to the Public Health Systems Reporting Requirements.

Dated: April 16, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–11078 Filed 5–5–03; 8:45 am]

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