submission of the current list of approved CMC information. Based on the number of annual reports received for approved NDAs and ANDAs in calendar year 2002, FDA estimates that approximately 2,589 annual reports will be submitted by approximately 295 applicants for approved NDAs, and approximately 4,991 annual reports will be submitted by approximately 240 applicants for approved ANDAs. FDA estimates that it will take an applicant approximately 1 hour to prepare and attach the list of approved CMC information as requested in the draft guidance.

FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

	No. of Respondents	Annual of Responses per Respondent	Total Responses	Hours per Response	Total Hours
NDAs	295	9	2,589	1	2,589
ANDAs	240	21	4,991	1	4,991
Total Hours					7,580

To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to *fyokata@omb.eop.gov* or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Desk Officer for FDA, FAX: 202–395–6974.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21985 Filed 8–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0165]

Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period on the draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' The agency issued this draft guidance in the **Federal Register** of May 6, 2003 (68 FR 24005). The initial comment period closes on September 3, 2003. To provide interested persons additional time to review the draft guidance and submit comments, the agency has decided to extend the comment period.

DATES: Written comments on the draft guidance may be submitted by November 3, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Division of Dockets Management (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–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9040, e-mail: *Sylviad@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is extending the comment period on the draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' This draft guidance is intended to provide recommendations on how to comply with current good manufacturing practice (CGMP) regulations 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.

The agency issued this draft guidance on May 6, 2003. The initial comment period closes on September 3, 2003, but at the request of the medical gas industry, the agency has decided to extend the comment period for an additional 60 days, until November 3, 2003.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance . Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this draft guidance for industry are available on the Internet 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: August 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21984 Filed 8–27–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given that the 37th meeting of the Substance Abuse and Mental Health Service Administration's (SAMHSA)