the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Importer's Entry Notice—(OMB Control Number 0910–0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Ensuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products, and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods, (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of goods to their final destinations; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at he same time he/she files an entry for import with the U.S. Custom Service. FDA uses this information to make admissibility decisions about FDA-regulated products offered for import into the United States.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 2002 was 5,496,954. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 53 percent of all entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents. Disclaimer entries are not FDA commodities.

In the **Federal Register** of May 23, 2003 (68 FR 28235), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801 for FY 2002 Updated	3,406	652	2,955,595	.14	413,833

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21982 Filed 8–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0191]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Submission of Validation Data for Reprocessed Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Submission of Validation Data for Reprocessed Single-Use Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 2003 (68 FR 40676), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0514. The approval expires on January 31, 2004.

A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: August 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21983 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–0364]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications; 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 ''Providing Regulatory Submissions in Electronic Format—

Annual Reports for NDAs and ANDAs.'' This draft guidance is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. The draft guidance discusses issues related to the electronic submission of annual reports for approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs) to FDA's Center for Drug Evaluation and Research (CDER). It is expected that the submission of these reports in electronic format will improve the agency's efficiency in processing, archiving, and reviewing the reports.

DATES: Submit written or electronic comments on the draft guidance by October 27, 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 Division 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 adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of 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: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, e-mail: *levinr@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs.'' The draft document provides guidance to industry regarding submission of annual reports in electronic format for approved NDAs and ANDAs. This draft guidance is consistent with the forthcoming guidance being developed on the submission of annual reports based on the Electronic Common Technical Document.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing annual reports for approved NDAs and ANDAs in electronic format. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. 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 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. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques and other forms of information technology, when appropriate.

Title: Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs.

Description: FDA is issuing a draft guidance for industry on the electronic submission of annual reports for approved NDAs and ANDAs. The guidance is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. It is expected that the submission of these reports in electronic format will improve the agency's efficiency in processing, archiving, and reviewing the reports.

Sections 314.70(d), 314.81(b)(2), and 314.98 of FDA regulations (21 CFR 314.70(d), 314.81(b)(2), and 314.98) provide reporting requirements for submitting annual reports for approved NDAs and ANDAs. Section 314.81(b)(2) and FDA Form 2252 (Transmittal of Periodic Reports for Drugs for Human Use) specify the information required in the submission of annual reports. The submission of annual reports under these regulations, including FDA Form 2252, is approved by OMB until March 31, 2005, under OMB control number 0910–0001. The draft guidance states that this information, currently required to be submitted on paper, may be submitted in electronic format as described in the draft guidance.

The draft guidance also requests information that is not specifically required in the regulations and is not approved by OMB under control number 0910–0001. Section 314.81(b)(2)(iv) requires that chemistry, manufacturing, and controls (CMC) changes be submitted in the annual report. To facilitate the review of this information, the draft guidance requests that applicants provide in electronic format a current list of approved CMC information to better document the changes occurring in applications. This information is currently requested in paper format in the guidance for industry entitled ''Format and Content for the CMC Section of an Annual Report'' (September, 1994) (see sections I and IV of part IV. Format and also attachment 1 of the guidance). The draft guidance requests that the list of approved CMC information include all information shown in attachment 1 of the September 1994 guidance, including: (1) The type and date of each change to each component; (2) the type of submission used to report the change (original, supplemental, or annual report); and (3) the date the change was reported and approved, if applicable.

Description of Respondents: Applicants that are required to submit annual reports updating information in an approved NDA or ANDA.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for the

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]

BILLING CODE 4160–01–S

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)