

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information as requested in the draft guidance.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]

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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Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases; Availability; Extension of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is extending the comment period on the draft guidance for industry entitled "Current Good Manufacturing Practice for Medical Gases." The agency issued this draft guidance in the *Federal Register* of May 6, 2003 (68 FR 24005).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 To provide interested persons additional time to review the draft guidance and submit comments, the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DATES: Written comments on the draft guidance may be submitted by November 3, 2003.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)

Center for Substance Abuse Treatment (CSAT) National Advisory Council will be held in September 2003.

A portion of the meeting is open and includes discussion of the Center's policy issues and current administrative, legislative, and program developments. The Council's meeting will include reports on Proposed Standard Funding Mechanisms; SAMHSA's Competitive Sourcing Activities; Collaboration with other Health and Human Services (HHS) Agencies; Overview of SAMHSA's Center for Substance Abuse Prevention's Programs and Initiatives; National Institute on Drug Abuse's Clinical Trials Network; Methadone Deaths; How Sovereignty Impacts Funding for Native Americans; Partners for Recovery Initiative; and Nicotine/Tobacco Substance Abuse and Mental Health Issues. In addition, the CSAT Director will provide an update on CSAT's program and activities.

The meeting will also include the review, discussion, and evaluation of individual grant applications. Therefore a portion of the meeting will be closed to the public as determined by the SAMHSA Administrator, in accordance with Title 5 U.S.C. 552b (c) and (6) and 5 U.S.C. App. 2, Sec. 10(d).

SAMHSA/CSAT welcomes the attendance of the public at its advisory committee, and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please inform the contact person at least 7 days in advance of the meeting. Substantive program information, a summary of the meeting and a roster of Council members may also be obtained from the contact person.

Committee Name: Center for Substance Abuse Treatment National Advisory Council.

Meeting Dates: September 16—8:30 a.m.—4:30 p.m.; September 17—8:30 a.m.—12:30 p.m.

Place: Sheraton Four Points Hotel, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Type: Closed: September 16, 2003—8:30 a.m.—10 a.m.; Open: September 16, 2003—10 a.m.—4:30 p.m.; Closed: September 17, 2003—8:30 a.m.—9:30 a.m.; Open: September 17, 2003—9:30 a.m.—12:30 p.m.

FOR FURTHER INFORMATION CONTACT: Cynthia Graham, NAC Executive Secretary, SAMHSA/CSAT NAC, 5600 Fishers Lane, RW II, Ste 619, Rockville,

MD 20857, (301) 443-8923, Fax: (301) 480-6077.

Dated: August 21, 2003.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03-21979 Filed 8-27-03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary for Management, Homeland Security.

ACTION: Submission for OMB review; comment request.

DATE: August 22, 2003.

SUMMARY: The Department of Homeland Security (DHS) has submitted the following (see below) information collection request (ICR), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Homeland Security, Theresa M. O'Malley ((202) 358-3571), or by e-mail to: *Terry.OMalley@dhs.gov*.

Comments: Comments and questions concerning this ICR listed below should be forwarded to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for Homeland Security, Office of Management and Budget, Room 10235, Washington, DC 20503 (Fax (202) 395-6974).

Comments must be received by September 29, 2003. The Office of Management and Budget is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- Enhance the quality, utility, and clarity of the information to be collected; and

- Minimize the burden of the collection of information on those who are to respond, including through the

use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Agency: Department of Homeland Security, Under Secretary of Management, Office of the Chief Information Officer.

Title: Supplemental Investigative Data.

OMB Number: 1620-0001.

Agency Form Number: SSF 86A.

Frequency: On occasion—reporting.

Affected Public: Individuals or households; Federal Government; State, Local or Tribal Government.

Number of Respondents: 10,000.

Estimated Time Per Respondent: 3 hours.

Total Burden Hours: 30,000.

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintaining): \$250,000 (\$25 per application × 10,000).

Description: Respondents are all Secret Service applicants. Applicants approved for hire require a Top Secret Clearance, and possibly Special Compartmented Information (SCI) Access. Responses to questions on the SSF 886A form provide information necessary for the adjudication for eligibility of the clearance, as well as ensuring that the applicant meets all internal agency requirements.

Steven I. Cooper,

Chief Information Officer.

[FR Doc. 03-22056 Filed 8-25-03; 2:39 pm]

BILLING CODE 4410-10-P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Notice of Cancellation of Customs Broker License

AGENCY: Bureau of Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: General notice.

SUMMARY: Pursuant to section 641 of the Tariff Act of 1930, as amended, (19 U.S.C. 1641) and the Customs Regulations (19 CFR 111.51), the following Customs broker license and any and all associated local and national permits are canceled without prejudice: