

child's progress toward the goals listed in the child's case plan and particularly for youth 17 years of age and above related to independent living and/or educational plans. ORR-4 is also

submitted as a baseline report along with the initial ORR-3 report for 17 years old and above youth, and as a follow-up annual report for cases that have terminated and are 17 to 21 years

old. ORR regulations at 45 CFR 400.120 describes specific URM program reporting requirements.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-3	15	75	0.25 (15 Minutes).	281.25
ORR-4	15	119	1.5 (1 Hour and 30 Minutes).	2,677.5

Estimated Total Annual Burden Hours: 2,958.75.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1197]

Draft Guidance for Industry on Certification of Designated Medical Gases; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Certification Process for Designated Medical Gases." This draft guidance describes the new certification process created by the Food and Drug Administration Safety and Innovation Act (FDASIA) for certain medical gases and explains how FDA plans to implement that process.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 19, 2013. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance and attached Form 3864 by February 19, 2013.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002; or the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Michael Folkendt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1900; or Germaine Connolly, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8331.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Certification Process for Designated Medical Gases." This guidance is intended to help persons or entities interested in requesting a certification for a designated medical gas under the new approval process for designated medical gases created by FDASIA (Pub. L. 112-144, 126 Stat. 993).

Title XI, subtitle B, of FDASIA added sections 575 and 576 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which created a certification process for designated medical gases. Specifically, section 575 provides that oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, carbon monoxide, and medical air are designated medical gases. Section 576 permits any person, beginning on January 5, 2013, to request a certification of a medical gas for certain indications and describes when FDA will grant or deny these requests.

This draft guidance explains how FDA plans to implement this new certification process. Specifically, the draft guidance describes the medical gases that are eligible for certification, who should submit a certification request, what information should be submitted, and how FDA will evaluate and act on the request. The draft guidance also describes how the new certification requirement will be enforced and describes FDA's intent to exercise enforcement discretion in certain instances.

FDA has also developed a form to help requestors submit their certification requests. FDA recommends that requestors use this form. The form

and an instructions page for use in completing the form are attached to this draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the Agency's current thinking on the certification process for designated 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 that approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 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 collection of information associated with this draft guidance, FDA invites comments on these 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 of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Request for Certification Process for Designated Medical Gas.

Description of Respondents: Respondents to this collection of information are manufacturers and/or marketers of certain medical gas drug products.

Burden Estimate: Under section 576 of the FD&C Act and the draft guidance, the following information would be submitted to FDA by a person requesting certification of a designated medical gas product: The requestor's name, address, and other contact information; the name, address, and other contact information of the manufacturing facilities involved in the production of the gas; and certain affirmations that the gas meets applicable compendial standards and that the product is manufactured in accordance with current good manufacturing practice. Requestors will make certification requests using FDA Form 3864 and will include a cover letter explaining the nature of the submission (as explained in the Instructions page to the form). In certain

circumstances FDA may ask followup questions if additional information is needed from the requestor to determine whether a medical gas qualifies for certification as a designated medical gas.

Based on our knowledge of the medical gas marketplace, we estimate that a total of approximately 50 requestors ("number of respondents" in table 1) will submit certification requests for designated medical gases in 2013. We expect that a small number (we estimate five) of these requestors will need to resubmit their certification requests, which we also expect to occur in 2013. Thus, for 2013, we estimate approximately 55 "total responses" in table 1. In 2014 and beyond we expect to receive only a small number of submissions. We estimate 5 per year, and estimate 1 out of 10 such submissions will require resubmission, for a total of 5.5 annualized responses (as reflected in table 2). Those submissions would consist of new certification requests, resubmissions, and postapproval submissions to provide FDA with updated information (e.g., a change of ownership or closure of a particular manufacturing facility). In every case the requestor should submit a new Form 3864 together with a cover letter explaining the nature of the submission. For all submissions, we estimate that preparing and submitting the form and cover letter to FDA will take approximately 2 hours per requestor ("average burden per response" in the tables in this document). This estimate includes the time that some requestors may need to reply to followup questions by FDA.

TABLE 1—ESTIMATED 2013 REPORTING BURDEN ¹

	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total hours
Form FDA 3864 and other requested information.	50	1.1	55	2	110

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN IN 2014 AND SUBSEQUENT YEARS ¹

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Form FDA 3864 and other requested information.	5	1.1	5.5	2	11

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

III. Comments

Interested persons may submit either written comments regarding this

document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to [http://](http://www.regulations.gov)

www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket

number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the

agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Transformation Accountability Reporting System—(OMB No. 0930-0285)—Extension

The Transformation Accountability (TRAC) Reporting System is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. A wide range of client and program information is captured through TRAC for approximately 700 grantees. This request includes an extension of the currently approved data collection effort.

This information collection will allow SAMHSA to continue to meet the Government Performance and Results Act (GPRA) of 1993 reporting requirements that quantify the effects and accomplishments of its programs, which are consistent with OMB guidance. In order to carry out section 1105(a)(29) of GPRA, SAMHSA is required to prepare a performance plan for its major programs of activity. This plan must:

- Establish performance goals to define the level of performance to be achieved by a program activity;
- Express such goals in an objective, quantifiable, and measurable form;
- Briefly describe the operational processes, skills and technology, and the human, capital, information, or other resources required to meet the performance goals;
- Establish performance indicators to be used in measuring or assessing the relevant outputs, service levels, and outcomes of each program activity;

- Provide a basis for comparing actual program results with the established performance goals; and

- Describe the means to be used to verify and validate measured values.

In addition, this data collection supports the GPRA Modernization Act of 2010 which requires overall organization management to improve agency performance and achieve the mission and goals of the agency through the use of strategic and performance planning, measurement, analysis, regular assessment of progress, and use of performance information to improve the results achieved. Specifically, this data collection will allow CMHS to have the capacity to report on a consistent set of performance measures across its various grant programs that conduct each of these activities. SAMHSA's legislative mandate is to increase access to high quality substance abuse and mental health prevention and treatment services and to improve outcomes. Its mission is to improve the quality and availability of treatment and prevention services for substance abuse and mental illness. To support this mission, the Agency's overarching goals are:

- **Accountability**—Establish systems to ensure program performance measurement and accountability
- **Capacity**—Build, maintain, and enhance mental health and substance abuse infrastructure and capacity
- **Effectiveness**—Enable all communities and providers to deliver effective services

Each of these key goals complements SAMHSA's legislative mandate. All of SAMHSA's programs and activities are geared toward the achievement of these goals and performance monitoring is a collaborative and cooperative aspect of this process. SAMHSA will strive to coordinate the development of these goals with other ongoing performance measurement development activities.

The total annual burden estimate is shown below:

ESTIMATES OF ANNUALIZED HOUR BURDEN—CMHS CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS

Type of response	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage cost	Total hour cost
Client-level baseline interview	15,681	1	15,681	0.48	7,527	\$15	\$112,903
Client-level 6-month reassessment interview	10,637	1	10,637	0.367	3,904	15	58,557
Client-level discharge interview ²	4,508	1	4,508	0.367	1,776	15	26,644
Client-level baseline chart abstraction ³	2,352	1	2,352	0.1	235	15	3,528
Client-level reassessment chart abstraction ⁴	8,703	1	8,703	0.1	870	15	13,055
Client-level discharge chart abstraction ⁵	8,241	1	8,241	0.1	824	15	12,362