4160-01-P

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Draft Guidance for Industry on Certification of Designated Medical Gases; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Certification Process for Designated Medical Gases." This draft guidance describes the new certification process created by the Food and Drug Administration Safety and Innovation Act (FDASIA) for certain medical gases and explains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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance and attached Form 3864 by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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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FDA is announcing the availability of a draft guidance for industry entitled "Certification Process for Designated Medical Gases."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 (Public Law 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]					
	No. of Respondents	No. 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]					
	No. of Respondents	No. 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://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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