



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Certification Process for Designated Medical Gases; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled “Certification Process for Designated Medical Gases.” This guidance explains how FDA administers the certification process and describes the annual reporting requirements for designated medical gases (DMGs). Specifically, the guidance discusses what products qualify as DMGs, who must submit a certification request, what information must be submitted, and how FDA will evaluate and act on the request. This draft guidance is being issued to reflect new and revised regulations in several areas to reduce the regulatory burden, as appropriate, for the medical gas industry. This draft guidance revises and replaces the draft guidance of the same name issued in November 2015, which was withdrawn on December 18, 2025.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF THE PUBLICATION OF THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-1197 for "Certification Process for Designated Medical Gases." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. 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.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm 4192, Silver Spring, MD 20993-0002, 301-796-6341, CDER-Quality-Policy@fda.hhs.gov or Scott Fontana, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-0656, AskCVM@fda.hhs.gov.

With regard to the proposed collection of information: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5683, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Certification Process for Designated Medical Gases.” This guidance revises and replaces the draft guidance of the same name (80 FR 73771, November 25, 2015) which made recommendations intended to help persons interested in requesting certification of a DMG under the process established by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144). The 2015 draft guidance was withdrawn on December 18, 2025.

FDASIA added sections 575, 576, and 577 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ddd, 360ddd-1, and 360ddd-2), which created a certification process for DMGs. Specifically, section 575 of the FD&C Act provides that oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, medical air, and carbon monoxide are DMGs. Section 576 of the

FD&C Act permits any person to request certification of a medical gas for certain indications and describes when FDA will grant or deny these requests.

On June 18, 2024, FDA issued a final rule (89 FR 51738) that established requirements more specifically tailored to medical gases to better address the unique characteristics of these drugs. The final rule was intended to reduce the regulatory burden, as appropriate, for the medical gas industry. This deregulatory effort addressed several areas in which either new regulations were needed or existing regulations required revision because they were not well-suited for medical gases. One area where new regulations were established was the certification of DMGs. Regulations that implement and clarify the certification process for DMGs described in section 576 of the FD&C Act are set forth in 21 CFR part 230.

FDA is issuing this revised draft guidance to align with the regulations for certification of DMGs that became effective on December 18, 2025, in accordance with the final rule. Revisions to the guidance include adding additional sections related to what information must be submitted, changes to a granted certification, annual reports, and withdrawal or revocation of approval. We also revised the discussion on labeling to align with the revised regulations in 21 CFR 201.161 and made editorial revisions to improve readability. We removed the attached certification request form; Form FDA 3864 and instructions for completing the form are now located at <https://www.fda.gov/about-fda/reports-manuals-forms/forms>.

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 current thinking of FDA on "Certification Process for Designated Medical Gases." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521), 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 following collection of information, we invite 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.

Cover Letter for Certification Requests;

OMB Control Number 0910-0906--Revision

This information collection helps support implementation of regulatory requirements that govern certification of DMGs. We have issued regulations in 21 CFR part 230, Certification and Postmarketing Reporting for Designated Medical Gases, setting forth applicable standards and procedures that include associated reporting and recordkeeping requirements.

We are revising the information collection to support the use of cover letters in connection with the certification process for certification requests, amendments, and

supplements. As we noted in our May 23, 2022, proposed rule regarding certification of DMGs (87 FR 31302), we recommend that the applicant include a cover letter describing the purpose of the certification request submission (e.g., original certification, amendment to supply additional information requested by FDA). The draft guidance for industry entitled “Certification Process for Designated Medical Gases” describes the recommended use of a cover letter when submitting certification requests. The draft guidance document is available for download at <https://www.regulations.gov/search?filter=FDA-2012-D-1197>.

All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> that utilizes topic-specific search terms. We intend to finalize the guidance document upon OMB approval of the attendant information collection.

The use of cover letters can assist stakeholders in more efficiently communicating requests for certification, amendments, or supplements. For example, in accordance with 21 CFR 230.70(a), if the original information submitted in connection with a certification request becomes incomplete or inaccurate at any time after the request has been deemed granted, the applicant must submit a supplement that includes a new certification request with updated information. As explained in section VII of the draft guidance, Changes to a Granted Certification, we recommend that an applicant also submit a cover letter with a new Form FDA 3864 clearly explaining the purpose of the submission and highlighting the updated information. We will use the context and information provided in the cover letters as we process certification requests.

Description of Respondents: Respondents to this information collection are entities who manufacture, process, pack, label, or distribute certain medical gases.

We estimate the burden of this collection of information as follows:

Table 1. Estimated Annual Reporting Burden¹

Certification Process for Designated Medical Gases Draft Guidance for Industry; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cover letter for certification request, amendment, or supplement.	9	1	9	1	9

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

We base our estimates on the number of certification request, amendment, and supplement respondents estimated in table 5 of the final rule entitled “Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases” published June 18, 2024 (89 FR 51738 at 51764). We assume all respondents submitting certification requests, amendments, or supplements will also submit a cover letter. We anticipate that respondents will be able to leverage information across the certification request, amendment, or supplement for use in the cover letter and estimate that it will take a respondent one hour to prepare and submit a cover letter.

This draft guidance also refers to previously approved FDA collections of information found in FDA regulations. The collections of information in 21 CFR part 230 relating to DMG certification requirements, certification requests using Form FDA 3864, and annual reporting using Form FDA 5025, as well as the collections of information in 21 CFR part 213 relating to current good manufacturing practice requirements for medical gases, including recordkeeping under 21 CFR 213.82 associated with receipt and storage of incoming DMGs, have been approved under OMB control number 0910-0906. The collections of information in 21 CFR 201.161 and 201.328 relating to labeling requirements for medical gas containers have been approved under OMB control number 0910-0572. The collections of information in 21 CFR part 207 relating to registration of producers of drugs and listing of drugs in commercial distribution have been approved under OMB control number 0910-0045. The collections of information in 21 CFR part 314 relating to new drug applications, including hearing procedures under 21 CFR 314.200, have been approved under OMB control number 0910-0001. The collections of

information in 21 CFR part 514 relating to new animal drug applications, including hearing procedures under 21 CFR 514.200, have been approved under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-02789 Filed: 2/11/2026 8:45 am; Publication Date: 2/12/2026]