NOTIFICATION

Addendum

The following communication, dated 21 June 2024, is being circulated at the request of the delegation of the United States of America.

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**Title:** Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases

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| **Reason for Addendum:** |
| [ ] | Comment period changed - date:  |
| [ ] | Notified measure adopted - date:  |
| [X] | Notified measure published - date: 18 June 2024 |
| [X] | Notified measure enters into force - date: 18 December 2025; This rule is effective 18 December 2025, except for the amendments to Sec. Sec. 4.2 (amendatory instruction 2), 4.3 (amendatory instruction 3), and 4.4 (amendatory instruction 4) (21 CFR 4.2, 4.3, and 4.4), which are effective 2 February 2026. The incorporation by reference of certain material listed in this rule has been approved by the Director of the Federal Register as of 2 February 2026. |
| [X] | Text of final measure available from[[1]](#footnote-1): <https://members.wto.org/crnattachments/2024/TBT/USA/final_measure/24_03898_00_e.pdf> |
| [ ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [ ] | Content or scope of notified measure changed and text available from1: New deadline for comments (if applicable):  |
| [ ] | Interpretive guidance issued and text available from1:  |
| [ ] | Other:  |

**Description:** The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule revising the requirements concerning current good manufacturing practice (CGMP), postmarketing safety reporting, and labeling that apply to certain medical gases. This final rule also establishes regulations regarding certification of designated medical gases. This final rule satisfies the medical gas rulemaking requirements of the Consolidated Appropriations Act, 2017.

This rule is effective 18 December 2025, except for the amendments to Sec. Sec. 4.2 (amendatory instruction 2), 4.3 (amendatory instruction 3), and 4.4 (amendatory instruction 4) (21 CFR 4.2, 4.3, and 4.4), which are effective 2 February 2026. The incorporation by reference of certain material listed in this rule has been approved by the Director of the Federal Register as of 2 February 2026.

89 Federal Register (FR) 51738, [Title 21](https://www.ecfr.gov/current/title-21) Code of Federal Regulations (CFR) Parts [4](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-4), [16](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-16), [201](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201), [210](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210), [211](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211), [213](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-213), [230](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-230), [314](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314), and [514](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-514):

<https://www.govinfo.gov/content/pkg/FR-2024-06-18/html/2024-13190.htm>

<https://www.govinfo.gov/content/pkg/FR-2024-06-18/pdf/2024-13190.pdf>

This final rule and the proposed rule notified as [G/TBT/N/USA/1870](https://eping.wto.org/en/Search?domainIds=1&documentSymbol=usa%2F1870) are identified by Docket Number FDA-2021-N-1333. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2021-N-1333/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov/) by searching the Docket Number.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)