CGA M-15—2017

Standard for Appropriate and Effective Regulations for Medical Gases within 21 CFR Parts 201, 205, and 210/211

SECOND EDITION

CGA
Compressed Gas Association
The Standard For Safety Since 1913

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Introduction

This standard reflects the Compressed Gas Association's (CGA) consensus position for how the Federal Food and Drug Administration's (FDA) regulations for finished pharmaceuticals found in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Parts 201 (labeling), 205 (wholesale distribution), and 210 and 211 (GMPs), should be revised for designated medical gases or combinations thereof. This standard is consistent with established and long standing industry practice yielding safe and efficacious designated medical gases and consistent with the Congressional intent in the *Food and Drug Administration Safety and Innovation Act*'s (FDASIA) identifying the need for revisions to 21 CFR [1, 2].[1]

For 21 CFR Part 201 only those sub-parts and sections where CGA has submitted proposed modifications to the FDA for designated medical gases and combinations thereof are included below. For 21 CFR Parts 205, 210, and 211, all sub-parts and sections are reproduced in this standard in their entirety with CGA's proposed modifications for designated medical gases and combinations thereof.

NOTE—CGA's modifications to the regulations identify new text with underlines and deleted text with strikeouts.

Title 21—Food and Drugs,
Chapter I—Food and Drug Administration,
Department of Health and Human Services
Subchapter C—Drugs: General

Part 201 Labeling

NOTE—Only includes those sub-parts and sections with proposed changes for designated medical gases and combinations thereof.

Subpart A—General Labeling Provisions

§ 201.1 Drugs; name and place of business of manufacturer, packer, or distributor.

(a) A drug or drug product (as defined in §320.1 of this chapter) in finished package form is misbranded under section 502 (a) and (b)(1) of the act if its label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor. This paragraph does not apply to any drug or drug product dispensed in accordance with section 503(b)(1) of the act.

(b) As used in this section, and for purposes of section 502 (a) and (b)(1) of the act, the manufacturer of a drug product is the person who performs all of the following operations that are required to produce the product: (1) Mixing, (2) granulating, (3) milling, (4) molding, (5) lyophilizing, (6) tableting, (7) encapsulating, (8) coating, (9) sterilizing, and (10) filling sterile, aerosol, or gaseous drugs into dispensing containers, and (11) filling designated medical gases or combinations thereof into containers by any of the following processes: (a) liquid to liquid, (b) liquid to gas, or (c) gas to gas.

(c) If no person performs all of the applicable operations listed in paragraph (b) of this section, no person may be represented as manufacturer except as follows:

(1) If the person performs more than one half of the applicable operations listed in paragraph (b) of this section and acknowledges the contribution of other persons who have performed the remaining applicable operations by stating on the product label that "Certain manufacturing operations have been performed by other firms."; or

(2) If the person performs at least one applicable operation listed in paragraph (b) of this section and identifies by appropriate designation all other persons who have performed the remaining applicable operations, e.g., "Made by (Person A), Filled by (Person B), Sterilized by (Person C)"; or

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.