CGA

Compressed Gas Association

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GENERAL GUIDE FOR THE MANUFACTURE OF MEDICAL GASES CLASSIFIED AS DRUGS

SECOND EDITION

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NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendix A (Informative) is for information only.

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1 Introduction

This publication describes the minimum requirements for manufacturing compressed medical gases (CMG) classified as drugs and is intended to aid the manufacturer in complying with the applicable regulations of the U.S. Food and Drug Administration (FDA) and various state agencies, e.g., departments of health and boards of pharmacy. For specific information on federal regulations, see Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) [1].[1]

This publication describes the information that shall be addressed in a firm's standard operating procedures (SOP) in order to be in compliance with current regulations. This publication also includes information that should be contained in a firm's SOP. It may not contain the information necessary to comply with all federal and state regulations, so it should be used in conjunction with other compliance publications and guidelines. It is the responsibility of the CMG manufacturer to ensure that their SOP comply with all applicable federal and state regulations.

2 Scope

This publication applies to firms that engage in the filling, repackaging, transfilling, mixing, and/or re-labeling of CMG classified as drugs by the FDA and applicable state agencies. Although it is primarily intended for firms engaged in the CMG manufacturing processes, portions may apply to firms that only distribute CMG classified as drugs.

This publication does not apply to:

- bulk air separation manufacturing and distribution facilities that produce United States Pharmacopoeia/National Formulary (USP/NF) products;
- bulk carbon dioxide USP manufacturing and distribution facilities;
- bulk helium USP manufacturing and distribution facilities;
- bulk nitrous oxide USP manufacturing and distribution facilities;
- drugs that are defined as Investigational New Drug Applications, e.g., a gas or gas mixture that has never been previously used as a drug, New Drug Applications, or Amended New Drug Applications by the Federal *Food, Drug, and Cosmetic Act* (the Act) [2];
- medical gases classified by FDA as medical devices as defined by the Act [2];
- gases labeled for industrial use and recreational applications, e.g., diving gases, self-contained breathing apparatus, aviator's breathing oxygen; or
- refrigerated liquid oxygen USP that is filled at a patient's residence or is filled, repackaged, transfilled, and/or relabeled by home respiratory care companies.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Adulterated

Drug product that does not meet all required or claimed standards of purity, strength, identity, or quality, or that contains a foreign substance that may be injurious to health.

NOTE—A drug product not manufactured in accordance with current good manufacturing practice (CGMP) may also be considered adulterated. See Section 501 of the Act [2].

3.2 Air liquefaction

Process by which air is separated into its component parts by cryogenic distillation.

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