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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3043]

Compressed Medical Gases-Warning Letters for Specific Violations Covering Liquid and Gaseous Oxygen; Withdrawal of Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide (CPG) Section 435.100, entitled "Compressed Medical Gases--Warning Letters for Specific Violations Covering Liquid and Gaseous Oxygen."

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Mary E. Kennelly, Office of Regulatory Affairs, 10903 New Hampshire Ave., Bldg. 32, rm. 4338, Silver Spring, MD 20993, 240-402-9577.

SUPPLEMENTARY INFORMATION: A Compliance Policy Guide (CPG) on medical gases was originally issued on November 5, 1987, in the Agency's Manual of Compliance Policy Guides. In a notice published in the Federal Register of September 16, 1992 (57 FR 42757), FDA announced the availability of a revised CPG on this topic entitled "Compressed Medical Gases--Warning Letters for Specific Violations Covering Liquid and Gaseous Oxygen" (CPG 7132a.16). Subsequently, the Agency's Manual of Compliance Policy Guides was reorganized

and this material became Section 435.100. The CPG provided guidance to FDA district offices for issuing warning letters to firms that are engaged in filling cylinders with gas(es) for medical use that are not operating in conformance with the adulteration, misbranding, and/or new drug provisions of the Federal Food, Drug, and Cosmetic Act.

On March 15, 2015, FDA implemented the revised Compliance Program Guidance Manual (CPGM) 7356.002E, entitled "Compressed Medical Gases," available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/ComplianceProgramManual/UCM125417.pdf>. CPGM 7356.002E instructs FDA staff regarding a range of subjects, including, but not limited to, the inspections and investigations, regulatory and/or administrative action, and the issuance of warning letters related to compressed medical gases. As the CPGM 7356.002E articulates FDA's current thinking on issuing warning letters related to compressed medical gases, CPG Section 435.100 is withdrawn.

Dated: August 28, 2015.

Steven Solomon,

Deputy Associate Commissioner for Regulatory Affairs.

4164-01-P

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