DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 28 2001

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Carl T. Johnson
President
Compressed Gas Association, Inc.
1725 Jefferson Davis Highway, Suite 1004
Arlington, VA 22202-4102

Re: Docket No. 95P-0188/CP1

Dear Mr. Johnson:

This responds to your citizen petition, submitted on behalf of the Compressed Gas Association, Inc. (CGA), and dated June 20, 1995, requesting that the Food and Drug Administration (FDA) amend 21 CFR part 205 to exempt persons engaged in the wholesale distribution of medical gases in interstate commerce from the requirement in § 205.4 to be State licensed as a wholesale distributor.

The CGA asserts that medical gas distributors should be exempted from the State licensing requirement in part 205 because of certain factors that distinguish medical gases from other types of prescription drug products and were not considered by Congress when the Prescription Drug Marketing Act (PDMA) was enacted (Petition at 1). According to your petition, these factors make Congress' findings in enacting PDMA, which appear in section 2 of the PDMA, inapplicable to medical gases. The factors you cite include: the use of "gas specific connections at both the manufacturer's and user's sites that preclude the use of the wrong gas" (Petition at 1); a relatively small distribution area (Petition at 2); the use of "dedicated filling equipment" (Petition at 2); the high cost of containers (Petition at 2); the nonexistence of a diversion market for medical gases (Petition at 2); the lack of reimported medical gases (Petition at 2); and the lack of use of drug samples for medical gases (Petition at 2-3). You state that, while the application of PDMA requirements to medical gases places a burden on the industry, it will not significantly reduce the risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers (Petition at 3).

In the *Federal Register* of December 3, 1999, the Agency published a final rule implementing those provisions in PDMA not already implemented in part 205 (64 FR 67720). As discussed in the preamble to the final rule, the Agency has determined that, with the exception of blood and blood components intended for transfusion, the PDMA and parts 203 and 205 of the Agency's regulations (21 CFR parts 203 and 205) apply to all prescription drug products. The application of the PDMA to medical gases was specifically discussed by the agency in the preamble: "[A]ll medical gases (i.e., oxygen, USP (United States Pharmacopeia); nitrogen, NF (National Formulary); nitrous oxide, USP; carbon dioxide, USP; helium, USP; and medical air, USP) are prescription drugs

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within the scope of PDMA" (67 FR 67220 at 67722). Therefore, all persons engaged in the wholesale distribution of medical gases in interstate commerce must be State licensed under part 205 and are subject to all other requirements under PDMA, including applicable requirements in part 203.

The Agency recognizes the differences in the distribution systems of medical gases and other types of prescription drugs. As you state, medical gases are typically distributed by small companies within a regional area that conduct refilling and other operations that qualify them as manufacturers and subject them to current good manufacturing practice (CGMP) requirements. Moreover, the Agency is aware that the practice of using drug samples for marketing purposes does not currently exist in the medical gas industry.[1] On the other hand, the Agency disagrees with the assertion that the diversion market for medical gases or potential for diversion of medical gases is nonexistent. Although the size of medical gas containers and the refill distribution system may limit the extent to which containers are stolen or are otherwise diverted, this does not mean that medical gases themselves may not be diverted or that a diversion market does not exist for such products. For example, the Agency is aware that nitrous oxide, USP is a drug for which an illegal submarket exists and which may have a large diversion potential.

You assert that Congress did not intend for PDMA to apply to medical gases because they are distributed differently than other types of prescription drugs and because certain provisions of PDMA (i.e., the drug sample provisions) may not apply to medical gas distribution. PDMA expressly applies to all prescription drugs. Neither PDMA nor its legislative history indicate that Congress intended to exempt wholesale distributors of medical gases from the requirement to be State licensed or from other PDMA requirements.

For the reasons stated above, your petition is denied. I hope this letter has been responsive to your concerns and apologize for any inconvenience the delay in responding may have caused.

Sincerely yours,

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

[1] As stated in the preamble to the December 3, 1999, final rule, the drug sample provisions of PDMA and part 203 "should have no practical applicability to the medical gas industry" (64 FR 67720 at 67722).