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December 9, 2003

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: COMMENT to Docket No. 2003N-0456
Agency Information Collection Activities; Proposed Collection; Comment Request;
Prevention of Medical Gas Mix-ups at Health Care Facilities

Dear Sir or Madam:

The Compressed Gas Association ("CGA") appreciates the opportunity to comment on the FDA's notice of data collection regarding mix-ups of medical gases.

CGA, founded in 1913, is dedicated to the development and promotion of safety standards and safe practices in the industrial and medical gas industry. We represent over 150 member companies in all facets of the industry – manufacturers, distributors, suppliers, and transporters of gases, cryogenic liquids, and related products and services. Through a committee system, CGA creates technical specifications, safety standards, training and educational materials. It works with government agencies to formulate responsible regulations and standards and to promote compliance with these regulations.

Because of CGA's commitment to safety, we favor initiatives that will further reduce the small number of medical gas mix-ups that occur. CGA has cooperatively engaged with FDA on such initiatives in the past. For example, in 2000, the CGA issued a safety bulletin (SB-26) to prevent workers at health care facilities ("HCFs") from removing product-specific container connections that were specifically designed to prevent mix-ups. In 2002, CGA identified the root causes of medical gas mix-ups, developed potential preventative solutions, and presented those results to the FDA. We worked with FDA to develop and distribute safety posters to warn HCF workers not to circumvent designed safety mechanisms. (These posters are currently available on both FDA's and CGA's websites: "Won't Connect? – Don't Connect!")

As we stated in our recent comments on the Agency's draft Guidance for medical gas cGMPs, most of the few mix-ups have occurred downstream from the manufacturer, when the medical gases were beyond the manufacturer's control. We noted approvingly the Agency's efforts to communicate with HCFs about safe practices to prevent mix-ups. In most of the mix-ups described by the Agency in the draft Guidance, the HCF and/or the HCF worker did not follow CGA safety standards, which—if followed—would have prevented the mix-up.

We understand from this notice that (1) FDA is concerned about medical gas mix-ups that have occurred at health care facilities, (2) FDA has investigated these mix-ups and concluded the cause was the connection of gases other than oxygen to the facilities' oxygen supply lines, and (3) the survey seeks to gauge the extent to which HCFs comply with safety measures designed to prevent mix-ups.

To the extent this notice recognizes that reducing errors by HCF staff is the key to reducing mix-ups, CGA whole-heartedly applauds the Agency's effort to assess these risks. In our view, the Agency is posing exactly the right question: what safety measures are HCFs taking to prevent mix-ups? That question, however, should be directed at HCFs, not at manufacturers/fillers of medical gases. As we elaborate below, this survey appears to ask the right question but of the wrong institutions. Our responses are ordered according to the topics on which FDA invited public comment.

Topic 1: Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

Comment: CGA believes the data itself—what measures HCFs are taking to prevent mix-ups—would indeed enable the FDA to better perform its function of assessing risks to public health. HCFs possess that data, so a survey of HCFs would likely yield results with significant practical utility.

The notice, however, is ambiguous as to the population the Agency intends to survey. From the agency's apparent invocation of 21 CFR Parts 210 and 211 as the basis of its authority for this survey, we presume that the target population is medical oxygen manufacturers and fillers. If our presumption is correct, such a survey would not yield the results desired. Manufacturers/fillers simply do not possess information about measures taken by HCFs to prevent mix-ups. Moreover, manufacturers/fillers do not have the authority to ask such questions of HCFs. Of course, manufacturers/fillers could respond regarding their own (upstream) safety measures. But a survey of upstream measures would not illuminate the safety measures taken downstream to prevent mix-ups at HCFs. Assessing the measures taken by manufacturers/fillers is (rightly) not the stated objective of this survey.

The Agency would go much farther in obtaining the data sought by surveying HCFs directly, just as the Agency, in 2001, made recommendations directly to HCFs on how to avoid such mix-ups.

Topic 2: The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

Comment: CGA cannot comment definitively on the accuracy of FDA's estimated burden until several ambiguities surrounding the survey's methodology are clarified. For example, the notice provides no details about the number or complexity of the survey questions. As mentioned above, it does not identify the survey's target population. It also does not explain who will conduct the survey or how these surveyors would interact with HCFs.

Regardless of whether the target population is HCFs or manufacturers/fillers, the FDA appears to have severely underestimate the burden—at 15 minutes per respondent per year—that this survey would impose.

Topic 3: Ways to enhance the quality, utility, and clarity of the information to be collected.

Comment: We recommend that FDA focus its data collection effort only on those HCFs that utilize medical gases as part of their therapeutic practice.

Topic 4: Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Comment: FDA should develop the survey such that the respondents can complete the survey online. FDA should send an announcement of the survey's availability directly to HCFs.

In conclusion, we support the Agency's efforts to improve patient safety by preventing mix-ups of medical gases. We urge the Agency to address its worthwhile question—to what degree are HCFs complying with safety measures to prevent mix-ups—directly to HCFs. If instead FDA targets manufacturers/fillers, however, the survey will lack utility and significantly burden CGA's members, who possess neither the data sought nor the authority to obtain it. CGA appreciates FDA's consideration of our comments.

Sincerely,

Carl T. Johnson
President
Compressed Gas Association