BOC GASES

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Dockets Management Branch
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

COMMENT
[Docket No. 03D-0165]
Draft Guidance for Industry on Current Good Manufacturing Practice for Medical Gases
68 Federal Register 24005, May 6, 2003

Dear Sir or Madam:

BOC Gases appreciates the opportunity to comment on the Draft Guidance for Industry on the Current Good Manufacturing Practice for Medical Gases ("the draft Guidance"), which the U.S. Food and Drug Administration issued on May 6, 2003.

BOC Gases is in agreement with FDA's goal to assure the Medical Gas Industry operates within the scope of the GMP regulation to provide a safe and effective product to the public. The guidance, once issued, should provide clear and concise direction to the industry which will enable us to develop compliant programs and systems. It should also assure that these regulatory requirements are universally and consistently applied by FDA to all manufacturers and distributors who fall under their jurisdiction.

BOC Gases is a member of the Compressed Gas Association ("CGA"), and as such, has actively participated in formulating CGA's comments and positions. We support the position taken by the CGA which in our view not only attempts to improve the focus, clarity and applicability of the Guidance but also continues to foster the collaborative efforts that have already been displayed between the CGA and FDA.

We would like to make the following comments on several of the issues that in our opinion are critical.

1. BOC believes that the recommendation by FDA to segregate medical gas products on delivery trucks is not required if proper training and procedural controls are in place. As stated in the CGA response, not only do we feel this practice would not necessarily reduce the risk of mix ups or incorrect deliveries, it also could lead to unsafe loading conditions on the delivery trucks and could be in conflict with DOT requirements.

2. In keeping with our opinion that in the right circumstances, there is no meaningful difference between medical and industrial gases, we see no need to recommend or require that equipment needs to be dedicated to medical service. However, BOC agrees that a

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piece of equipment should be appropriately cleaned and qualified if it was in a service that was not considered to be within the scope of a GMP compliant quality system.

3. As described in length by the CGA, BOC firmly agrees that there is no justification of the need to perform yield calculations on medical gas products. The reasoning has been fully explained in the CGA document and BOC totally is in agreement with this position.

BOC looks forward to continuing a constructive and collaborative dialogue with FDA on these and all other issues that impact the medical gas business.

Regards,

Dennis A. King
Director, Safety, Health, Environmental,
Quality & Regulatory Affairs

cc: I. Gillespie - BOC Gases
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