

# Puritan-Bennett Medical Gases

Airgas

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July 28, 2000

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane - Room 1061- HFA-305  
Rockville, MD 20852

Re: Docket No. 00P-1406, Petition to Stay Fresh Air

Dear Madam or Sir:

Puritan Medical Products, Inc. is a medical gases manufacturer with facilities in major cities throughout the United States. Puritan Medical Products, Inc., d.b.a. Puritan-Bennett Medical Gases manufactures and distributes products to customers such as hospitals, home care providers, nursing homes, and doctors and dental offices. Since its inception as Kansas City Oxygen in 1913, our company has been in the medical gas business and has been a pioneer in the use of medical gases for anesthesia, respiratory therapy, and other medical treatments.

Puritan Medical Products, Inc. submits these comments to the above docket in support of the action requested in this Petition for Stay. Specifically, Puritan Medical Products, Inc. supports the position of the Petitioners that the agency must cease promulgating, presenting and otherwise issuing Fresh Air speeches and documents.

Puritan Medical Products, Inc. believes that frequent presentation of Fresh Air has been used by the FDA as an improper means to address deficiencies that cGMPs, designed specifically for drug products in traditional dosage forms, have when applied to medical gases. Substitution of Fresh Air for cGMPs without opportunity for effective public comment creates an unpredictable regulatory climate and is a significant regulatory burden on our company. We find this approach to enforcement of the FD&C Act particularly troublesome when the Agency fails to respond in a timely manner to Citizen's Petitions submitted by the Compressed Gas Association. These Petitions specifically address many of those deficiencies and represent best practices for the industry.

In addition, such presentations appear to contravene the FDA's own Good Guidance Practices and violate the Administrative Procedure Act. Fresh Air is simply not an appropriate medium for elucidating existing regulatory requirements or establishing new ones. Accordingly, Puritan Medical Products, Inc. urges the FDA to grant the Petition and stop all further presentations of Fresh Air, and furthermore, urges the Agency to properly promulgate regulations or guidance documents specifically applicable to the medical gas industry.

Sincerely,



William C. Fettes  
President

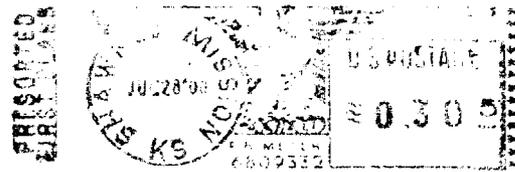
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