DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209927

DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST

General Air Service & Supply
Attention: Steve Bradney, Facility Manager
6330 Colorado Blvd.
Commerce City, CO 80022

Dear Mr. Bradney:

Please refer to your October 19, 2016, request, received on October 26, 2016, for certification of Medical Air, USP, as a designated medical gas. You have requested to market Medical Air, USP, for human use.

A request for certification of a medical gas as a designated medical gas submitted under section 575(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) is deemed to be granted unless, within 60 days of the filing of the request, FDA finds that one or more of the bases for denying the request listed at section 575(a)(2) of the FD&C Act applies. FDA has made no such finding in connection with your request, and 60 days have passed since your request was filed. Accordingly, by operation of section 575(a)(2) of the FD&C Act, your request for certification of Carbon Dioxide, USP as a designated medical gas is deemed to be granted, and you now have in effect an approved new drug application (NDA 209927) for this gas effective 12/25/2016.

We remind you that if you make any changes to the information in your certification request, such as where the gas is manufactured, how it is manufactured, or changes in applicant information, you will need to submit an updated certifications request to this same NDA application number. Please cite the NDA application number listed at the top of the first page of any communications concerning this application.

Send all correspondences concerning this application to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, call me at 301-796-1670.

Sincerely,

Michael M. Folkendt -S

Digitally signed by Michael M. Folkendt -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300085536, cn=Michael M. Folkendt -S
Date: 2018.01.11 14:58:33 -05'00'

Michael Folkendt
Associate Director for Regulatory Affairs (ADRA)
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
CDER/FDA