NDA 216307
NADA N-141-548

DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST

General Air Service & Supply Co.
Attention: Dave Thunselle, Safety and Compliance Manager
1105 Zuni Street
Denver, CO 80204

Dear Dave Thunselle:

Please refer to your May 27, 2021, request for certification of Helium, USP as a designated medical gas. You have requested to market Helium, USP, for both human and animal 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 Helium, USP, as a designated medical gas is deemed to be granted, and you now have in effect an approved new drug application (NDA 216307) and an approved new animal drug application (NADA N-141-548) for this gas effective 7/26/2021.

If any of the information you have submitted in connection with your request changes, such as where the gas is manufactured or changes in applicant information, you will need to submit an updated certifications request to these same NDA/NADA application numbers. please consult section IV.D of the draft guidance document entitled Certification Process for Designated Medical Gases (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM332136.pdf) for additional information. Please cite the NDA/NADA application numbers listed above at the top of the first page of any communications concerning these applications.

We encourage the submission of Designated Medical Gas submissions electronically via the CDER NextGen Portal located here: https://edm.fda.gov/EDMIDPLogin/welcome. If you choose to instead submit your application in paper, send the paper submissions, including those sent by overnight mail or courier, 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

Please do not mail any paper copies of submissions submitted via the CDER NextGen Portal.

If you have any questions, please contact Elisa Nickum, Regulatory Business Process Manager, at elisa.nickum@fda.hhs.gov or (301) 796-4226.

Sincerely,

Charles res FS
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Charles J. Andres, Ph.D.
Director Division of Business Information Science and Management
Office of New Animal Drug Evaluation, HFV-180
Center for Veterinary Medicine
FDA

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Michael M. Folkendt
Associate Director for Regulatory Affairs
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
FDA