NDA 220634
NADA N-141-611

**DEEMED GRANTED -**
**MEDICAL GAS CERTIFICATION REQUEST**

General Distributing Company
Attention: Daniel Hand
Plant Manager - Compliance Manager
430 17th Ave NE
Great Falls, MT 59404

Dear Daniel Hand:

Please refer to your April 17, 2025, request, received on April 17, 2025, for certification of Carbon Dioxide, USP as a designated medical gas. You have requested to market Carbon Dioxide, USP, for 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 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 220634) and an approved new animal drug application (NADA N-141-611) for this gas effective June 16, 2025.

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 Please consult section IV.D of the draft guidance document entitled Certification Process for Designated Medical Gases (available at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:

Central Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705

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

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

Sincerely,

*{See appended electronic signature page}*

Barbara Leotta
Deputy Office Director
Office of New Animal Product Evaluation
Center for Veterinary Medicine
FDA

*{See appended electronic signature page}*

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

Michael Folkendt

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Barbara Leotta

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