DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 215007
NADA N-141-537

DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST

Nexair, LLC
Attn: Randall Stroud
Quality Assurance Manager
1350 Concourse Ave.
Memphis, Tennessee 38104

Dear Mr. Stroud:

Please refer to your May 19, 2020, request received on May 19, 2020, for certification of Carbon Dioxide, USP as a designated medical gas. You have requested to market Carbon Dioxide, USP for human and animal drug 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 215007) for human drug use and an approved new animal drug application (NADA 141-537) for animal drug use for this gas effective 7/18/2020.

If any of the information you have submitted in connection with your request becomes incomplete or inaccurate, please consult section IV.D of the draft guidance document entitled *Certification Process for Designated Medical Gases* (available at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 instructions on providing FDA with complete, up-to-date information. Please address any such communications to:

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

Please include the NDA and NADA numbers listed above at the top of the first page of any such communications.

If you have any questions, please contact Christina Pleas at (240) 402-2873 or by email at Christina.Pleas@fda.hhs.gov.

Sincerely,

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

Michael Folkendt
Deputy Director (Acting)
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
CDER/FDA

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CHARLES J ANDRES
07/23/2020 08:14:15 AM

MICHAEL M FOLKENDT
07/30/2020 09:26:02 AM