



NDA 211270  
NADA 141-493

**DEEMED GRANTED -  
MEDICAL GAS CERTIFICATION REQUEST**

Linde Gas Puerto Rico Inc.  
c/o Linde North America Inc.  
Attn: Matt Hertzel, Healthcare Licensing Manager  
200 Somerset Corporate Blvd., Suite 7000  
Bridgewater, NJ 08807

Dear Mr. Hertzel:

Please refer to your October 16, 2017, request received on October 18, 2017, for certification of Medical Air, USP, as a designated medical gas. You have requested to market Medical Air, 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 Medical Air, USP as a designated medical gas is deemed to be granted, and you now have in effect an approved new drug application (NDA 211270) and an approved new animal drug application (NADA 141-493) for this gas effective 12/17/2017.

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you have submitted in connection with your request becomes incomplete or inaccurate, please consult section IV.D of the draft guidance document entitled *Certification Process for Designated Medical Gases* (available at 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

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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 Michael Folkendt at (301) 796-1670 or by email at [michael.folkendt@fda.hhs.gov](mailto:michael.folkendt@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  
Associate Director for Regulatory Affairs  
Office of Program and Regulatory Operations  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research  
FDA