



NDA 205864  
NADA 141395

**DEEMED GRANTED -  
MEDICAL GAS CERTIFICATION REQUEST**

Air Products and Chemicals, Inc.  
Attn: Edward J. Csira  
Team Lead, Quality and Regulatory Compliance  
7201 Hamilton Blvd  
Allentown, PA 18195-1501

Dear Mr. Csira:

Please refer to your May 21, 2013, request received on May 24, 2013, for certification of Helium, USP as a designated medical gas. You have requested to market Helium, 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 Helium, USP as a designated medical gas is deemed to be granted, and you now have in effect an approved new drug application (NDA 205864) and an approved new animal drug application (NADA 141395) for this gas.

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have submitted in connection with your request becomes incomplete or inaccurate, please consult section IV.D of the draft guidance document entitled *Certification Process for Designated Medical Gases* (available at 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

*{See appended electronic signature page}*

Charles J. Andres, Ph.D.  
Business Process Improvement Manager  
Office of New Animal Drug Evaluation  
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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MICHAEL M FOLKENDT  
09/25/2015

CHARLES J ANDRES  
09/28/2015

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