DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205911
NADA 141404

DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST

Praxair Distribution Mid-Atlantic, LLC
Attn: John Hercik
Praxair Distribution, Quality Assurance Manager
14788 York Road
North Royalton, OH 44133

Dear Mr. Hercik:

Please refer to your May 28, 2013, request received on June 6, 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 205911) and an approved new animal drug application (NADA 141404) 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you have submitted in connection with your request becomes incomplete or inaccurate, please consult section IV.D of the draft guidance document entitled *Certification Process for Designated Medical Gases* (available at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 New Drug Quality Assessment
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 call Michael Folkendt at (301) 796-1670.

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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/s/

CHARLES J ANDRES
09/25/2015

MICHAEL M FOLKENDT
09/25/2015