



NDA 214937

**DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST**

WestAir Gases & Equipment, Inc.
Attn: Keith Martinez
Director of Safety, Quality, & Compliance
2929 E. Dorothy Ave.
Fresno, California 93706
USA

Dear Mr. Martinez:

Please refer to your April 27, 2020, request received on April 28, 2020, for certification of Helium, USP as a designated medical gas. You have requested to market Helium, USP for human 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 214937) 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you have submitted in connection with your request becomes incomplete or inaccurate, please consult section IV.D of the draft guidance document entitled *Certification Process for Designated Medical Gases* (available at 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

Please include the NDA number 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,

Christina Pleas -S

Digitally signed by Christina Pleas S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People
0.9.2342.19200300.100.1.1=2001710492, cn=Christina Pleas S
Date: 2020.07.09 11:34:03 -0400

Christina Pleas, PharmD
Sr. Regulatory Project Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
Food and Drug Administration

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/

CHRISTINA J PLEAS
07/08/2020 04:30:16 PM