



NDA 213609
NADA N-141-523

**DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST**

Roberts Oxygen Company, Inc.
Attention: Ron Kirby, Production and Distribution Manager
17011 Railroad Street
Gaithersburg, MD 20877

Dear Mr. Kirby:

Please refer to your May 14, 2019, request, received on May 15, 2019, for certification of Helium, USP, as a designated medical gas. You have requested to market Helium, USP, for both human and animal 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 213609) for human drug use and an approved new animal drug application (NADA N-141-523) for animal drug use for this gas effective July 14, 2019.

We remind you that if you make any changes to the information in your certification request, such as where the gas is manufactured, how it is manufactured, or changes in applicant information, you will need to submit an updated certification request to these same application numbers. Send all correspondences concerning this application to the following address:

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 Michael Folkendt at (301) 796-1670 or by email at michael.folkendt@fda.hhs.gov.

Sincerely,

Charles J.
Andres -S

Digitally signed by Charles J.
Andres -S
Date: 2019.07.17 09:31:30
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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 M.
Folkendt -S

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Michael Folkendt
Deputy Director (Acting)
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
FDA