DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 213990
NADA N-141-525

DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST

ILMO Products Company
Attention: Kevin Miner, Safety Manager
7 Eastgate Drive
Jacksonville, IL 62650

Dear Mr. Miner:

Please refer to your August 21, 2019, request, received on August 28, 2019, for certification of Helium, USP, as a designated medical gas. You have requested to market Helium, USP, for both 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 213990) for human drug use and an approved new animal drug application (NADA N-141-525) for animal drug use for this gas effective 10/27/2019.

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 certifications 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 Christina Pleas at (240) 402-2873 or by email at Christina.Pleas@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
Deputy Director (Acting)
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
CDER/FDA

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/

MICHAEL M FOLKENDT
04/13/2020 01:25:12 PM

CHARLES J ANDRES
04/14/2020 09:22:40 AM

Christina Pleas

Digitally signed by Christina Pleas
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