DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 213507
NADA N-141-522

CORRESPONDENCE

A-OX Welding Supply Co., Inc.
Attention: Terran E. Bergdale, Ph.D.
Quality Control Unit Coordinator
101 N. Harlem Avenue
Sioux Falls, SD 57104

Dear Dr. Bergdale:

Please refer to your April 8, 2019, request, received on April 16, 2019, for certification of Carbon Dioxide, USP, as a designated medical gas.

We also refer to our June 26, 2019, Deemed Granted letter. In the second paragraph of that letter, we incorrectly indicated the wrong medical gas that was Deemed Granted in the sentence *"…your request for certification of Helium, USP as a designated medical gas is deemed to be granted…"*. The correct medical gas is indicated correctly in the first paragraph. Regardless, we are issuing a replacement Deemed Granted letter for your records. There are no other changes to the letter or your application and you still have in effect an approved new drug application (NDA 213507) for human drug use and an approved new animal drug application (NADA N-141-522) for animal drug use for this gas effective June 15, 2019.

I apologize for any inconvenience this error may have caused you.

If you have any questions, please contact Michael Folkendt at (301) 796-1670 or by email at michael.folkendt@fda.hhs.gov.

Sincerely,

Michael M. Folkendt -S

Digitally signed by Michael M. Folkendt -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300085536, cn=Michael M. Folkendt -S
Date: 2019.08.27 08:24:19 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 213507
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DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST

A-OX Welding Supply Co., Inc.
Attention: Terran E. Bergdale, Ph.D.
Quality Control Unit Coordinator
101 N. Harlem Avenue
Sioux Falls, SD 57104

Dear Dr. Bergdale:

Please refer to your April 8, 2019, request, received on April 16, 2019, for certification of Carbon Dioxide, USP, as a designated medical gas. You have requested to market Carbon Dioxide, 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 Carbon Dioxide, USP, as a designated medical gas is deemed to be granted, and you now have in effect an approved new drug application (NDA 213507) for human drug use and an approved new animal drug application (NADA N-141-522) for animal drug use for this gas effective June 15, 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: 2019.08.27 07:16:13 -04'00'

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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Date: 2019.08.27 08:25:12 -04'00'

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