DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209989
NADA 141477

DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST

Matheson Tri-Gas, Inc.
Attention: Bonnie J. Strange
Vice President, FDA Security and Emergency Response
1916 2nd Street NW
Albuquerque, NM 87102

Dear Ms. Strange:

We acknowledge receipt on October 25, 2016, of your September 30, 2016, request for Designated Medical Gas Certification submitted under Section 576 of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Description of Medical Gas:	Nitrous Oxide
Requested use:	both human and animal use
Indication:	for analgesia
Date of Application:	September 30, 2016
Date of Receipt:	October 25, 2016
Our Reference Numbers:	NDA 209989 (for human use) NADA N-141-477 (for 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 Nitrous Oxide as a designated medical gas is deemed to be granted, and you now have in effect an approved new drug application (NDA 209989) for human use and an approved new animal drug application (NADA N-141-477) for animal use 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you have submitted in connection with your request becomes incomplete or inaccurate, please consult section IV.D of the draft guidance document entitled *Certification Process for Designated Medical Gases* (available at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 both the NDA and NADA numbers listed above at the top of the first page of any such communications.

If you have any questions, call Michael Folkendt, Associate Director for Regulatory Affairs, 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,
HFV-100
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/

MICHAEL M FOLKENDT
01/06/2017

CHARLES J ANDRES
01/09/2017