



NDA 214858

**DEEMED GRANTED -
MEDICAL GAS CERTIFICATION REQUEST**

Air Liquide Canada Inc.
Attn: Alice Chen
Director of Regulatory and Quality Affairs
6-6990 Creditview Road
Mississauga, Ontario, L5N8R9
Canada

Dear Ms. Chen:

Please refer to your April 02, 2020, request received on April 03, 2020, for certification of Nitrogen, NF as a designated medical gas. You have requested to market Nitrogen, NF 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 Nitrogen, NF as a designated medical gas is deemed to be granted, and you now have in effect an approved new drug application (NDA 214858) 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you have submitted in connection with your request becomes incomplete or inaccurate, please consult section IV.D of the draft guidance document entitled *Certification Process for Designated Medical Gases* (available at 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, ou=U.S. Government, ou=HHS, ou=FDA, ou=People
9 9 2342 19200300 100 1 1=200710492, cn=Christina Pleas, S
Date: 2020.06.02 08:52:30 -04:00

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

CHRISTINA J PLEAS
06/29/2020 09:51:00 AM