DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Annual Report for Designated Medical Gas (21 CFR 230.80)

Form Approved:
OMB No. 0910-XXXX
Expiration Date:
Month XX, 20XX
See PRA Statement on last numbered page

FDA

1. APPLICANT INFORMATION

Applicant Name		
Address 1		
Address 2 *(if applicable)*		
City	State/Province/Region	ZIP or Postal Code
Country *(If not United States please provide contact information for authorized U.S. agent in "Contact Information" field below.)*		
CONTACT INFORMATION *(ENTER ADDRESS ONLY IF DIFFERENT FROM ABOVE.)*		
Last Name	First Name	Middle Name
Title		
Address 1		
Address 2 *(if applicable)*		
City	State	ZIP or Postal Code
Telephone Number	Email Address	Fax Number

2. PRODUCT INFORMATION

Name of designated medical gas *(select only one)*

☐ Oxygen, USP ☐ Nitrogen, NF ☐ Nitrous oxide, USP ☐ Carbon dioxide, USP
☐ Medical air, USP ☐ Helium, USP ☐ Carbon monoxide

Application number:

NDA number: _____ NADA number: _____

3. ANNUAL REPORT INFORMATION

Summary of Significant New Information

Distribution Data

Administrative Changes

(continued on next page)

PSC Publishing Services (301) 443-6740 EF

UPDATE FACILITY SECTION

3a. Facility Update

Name of Facility		
Address 1		
Address 2		
City	State/Province/Region	ZIP or Postal Code
Country *(If outside the United States)*		
Unique Facility Identifier *(e.g., DUNS Number)*	FEI Number *(if one exists)*	

☐ This facility was added since the last annual report
☐ This facility was removed since the last annual report

Add Continuation Page

4. SIGNATURE(S)

By my signature, I hereby certify that the data and information in this submission have been reviewed and, to the best of my knowledge, are true and accurate. WARNING: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

APPLICANT

Applicant Name	Title	
Signature of Applicant		Date *(mm/dd/yyyy)*

AUTHORIZED U.S. AGENT (IF APPLICABLE)

Name of Authorized U.S. Agent	Title	Telephone Number
Signature of Authorized U.S. Agent		Date *(mm/dd/yyyy)*

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