



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Annual Report for Designated Medical Gas
(21 CFR 230.80)

Form Approved:
OMB No. 0910-0906
Expiration Date:
February 29, 2028
See PRA Statement on
last numbered page



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)

UPDATE FACILITY SECTION		
Facility Update		
Name of Facility		
Address 1		
Address 2		
City	State/Province/Region	ZIP or Postal Code
Country <i>(If outside the United States)</i>		
Unique Facility Identifier <i>(e.g., DUNS Number)</i>		FEI Number <i>(if one exists)</i>
<input type="checkbox"/> This facility was added since the last annual report <input type="checkbox"/> This facility was removed since the last annual report		<input type="button" value="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 <i>(mm/dd/yyyy)</i>
AUTHORIZED U.S. AGENT (IF APPLICABLE)		
Name of Authorized U.S. Agent		Title
Signature of Authorized U.S. Agent		Telephone Number
		Date <i>(mm/dd/yyyy)</i>
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