



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



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**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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

-DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.-

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”