# — SAMPLE —

Form Approved: OMB No. 0910-0045. Expiration Date: September 30, 1997. See OMB Statement on Reverse.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

## DRUG PRODUCT LISTING

*(In accordance with Public Law 92-387)*

NAME AND ADDRESS OF FIRM: GAS Firm's Name and Address

LABELING REVISION — CHANGE OF: ☐ RTE OF A ADMIN ☐ INDICATION ☐ NAME / DOSE / STR / INGR ☐ OTHER *(Specify)*

If you are discontinuing or updating your product check this box and indicate type of change

| SEC | S | U | PRODUCT TRADE NAME OR CATALOG NAME | NATIONAL DRUG CODE LABELER | PRODUCT |
|---|---|---|---|---|---|
| 01 | | | NAME OF GAS OR GAS MIXTURES | 01234 | 5678 9 |

| FDA APPLICATION NO. | REPORT DATE MO | DA | YR | TYPE APPL | TYPES OF BUSINESS | PRODUCT TYPE | BNDD | LEGAL STATUS | SCHED | PROF USE | PRODUCT DISCONTINUED | BASIS OF CONCENTRATION WHOLE NUMBERS | DECIMAL | UNIT |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 02 | 16 | 97 | M | OTHER *(Specify)* TRANSFILLERS ARE Considered Manufacturers | H | | R | | | OTHER *(Specify)* | 1 | | LTR |

| DOSAGE FORM | ROUTES OF ADMINISTRATION 1 | 2 | 3 | OTH | PT | SEC | S | U | SMPL | PKG CODE | PACKAGE SIZE | PACKAGE TYPE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| GASINH NAS MISC | | | | | | 03 | | | | *1310 | FTC | CYLINDER |
| | | | | | | 03 | | | | *21180 | LITERS | |
| | | | | | | 03 | | | | *3215 | POUNDS | OR |
| | | | | | | 03 | | | | *4350 | GALLONS | |
| | | | | | | 03 | | | | **AS ORDERED | | DEWAR |

EXAMPLES ONLY

| MO | YEAR | MO | YEAR | MO | YEAR |
|---|---|---|---|---|---|
| | | | | | |

*NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than $1,000, or both (FDA&C Act, Section 303).*

| SEC | S | U | TYPE | PT | ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC. | AMOUNT WHOLE NUMBER | DECIMAL | UNIT |
|---|---|---|---|---|---|---|---|---|
| 05 | | | | | → LIST ALL GASES IN THE PRODUCT | | | |
| 05 | | | A | | OXYGEN | 995 | | %VV |
| 05 | | | A | | NITROGEN | | | |
| 05 | | | A | | CARBON DIOXIDE | 999 | | %VV |
| 05 | | | A | | NITROUS OXIDE | | | |
| 05 | | | | | | | | |
| 05 | | | | | | | | |
| 05 | | | | | | | | |
| 05 | | | | | | | | |
| 05 | | | | | | | | |

EXAMPLES ONLY

| SEC | S | U | SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER | ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT | STATE | FOREIGN COUNTRY | NDC LABELER CODE | SHORT NAME |
|---|---|---|---|---|---|---|---|---|
| 07 | | | 1234567 | WHERE YOU GET THE GAS | MD | | 123456 | |
| 07 | | | | and | | | | |
| 07 | | | | IF YOU ARE A TRANSFILLER - YOUR NAME GOES HERE ALSO | | | | |

FORM FDA 2657 (10/94) PREVIOUS EDITION IS OBSOLETE.

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