



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Surged by Kay Davis 2/10/98 3/14/98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

WARNING LETTER
98-DT-04

FEB 06 1998

Phillip Newbold, President and Chief Executive Officer
Memorial Health Systems
707 North Michigan Ave.
South Bend, Indiana 46601

Dear Mr. Newbold:

Investigator Myra Casey of our South Bend office inspected Memorial Home Care 17390 Dugdale Drive South Bend on December 11-17, 1997. The medical oxygen transfilled by this firm was misbranded within the meaning of Sections 502(a), 503(b)(4), 502(f)(1), and 502(o) of the Federal Food, Drug and Cosmetic Act (the Act). Oxygen USP is a drug within the meaning of Section 201(g) of the Act.

The medical oxygen is misbranded.

- 1) Oxygen USP, label for high pressure cylinders bears the incorrect statement, "For oxygen deficiency or emergency resuscitation when used by personnel instructed in oxygen administration. For other medical applications, use only as directed by a licensed practitioner."
- 2) Oxygen USP labeling fails to bear adequate directions for use in accordance with 21 CFR 201.100(c) and does not bear the statement "Caution: Federal law prohibits dispensing without a prescription."
- 3) Oxygen USP was transfilled in an establishment not duly registered under Section 510 of the Act and the article has not been listed as required by Section 510(j).

All medical gas drug labels should also bear the name and address of the manufacturer or distributor.

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Memorial Health Systems
South Bend, IN

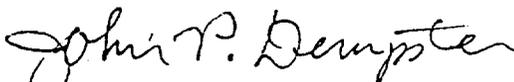
The above is not intended to be an all-inclusive list of violations at your firm. It is your responsibility to assure that your firm's products adhere to the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

We acknowledge the fact that Mr. Paul Laskowski, Director of Equipment and Supplies agreed during the inspection to register the subject establishment. Please verify that registration has been accomplished or indicate that you need the required forms and we can provide them.

I have enclosed a copy of Human Drug CGMP Notes December, 1996, which addresses a modified federal caution statement for emergency use as well as the Fresh Air '97' speech for your information.

Please notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct these violations and to prevent their recurrence. Your response should be directed to the attention of Mrs. Judith A. Putz, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Ave. Detroit, MI 48207 (Telephone: 313-226-6260 ext.137).

Sincerely yours,


for Raymond V. Mlecko
Acting District Director
Detroit District

Enclosures: a/s

cc: Michael J. O'Neil
Assistant Vice President and General Manager
Memorial Home Care
17390 Dugdale Drive
South Bend, IN 46635