



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

11-33900

FEB 8 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

*purged BRH
2/9/00*

Mr. Peter Lewis, President
Hyperbaric Technologies Incorporated
One Sam Stratton Road, PO Box 69
Amsterdam, NY 12010-0069

Dear Mr. Lewis:

We are in receipt of your correspondence dated October 22, 1999, with accompanying labeling materials in response to our informational letter dated September 27, 1999. The materials submitted revealed serious regulatory problems involving your hyperbaric chambers.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration (FDA) before they may offer them for sale. This helps to protect the public health by ensuring that new medical devices are shown to be both safe and effective or substantially equivalent to other devices already marketed in this country.

Our records do not show that you obtained marketing clearance for your Hyper-Oxy (Oxy AT, Hyper Bag, etc.) Hypertec Monocoque, Hypertec Oyster, or Hypertec Hybrid devices before offering the products for sale.

You stated in your October 22, 1999, correspondence to FDA that the Hyper-Oxy was originally cleared for marketing under K874752A. In reviewing the labeling and promotion and advertising materials, it became clear that K874752A dated February 2, 1988, would not cover the vast number of current indications. The original submission by [redacted] for the Gamow Hyperbaric Chamber, K874752A, stated that the indication was for acute mountain sickness. Any other indications not covered under K874752A require submission of a new 510(k). We refer you to the "Copies of Literature" section of the labeling you submitted October 22, 1999. The chamber known as the Hyper Oxy, Oxy AT, Hyper Bag, and all other names used in the

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marketing and distribution by [redacted] your exclusive marketer and distributor for this product, is in violation of the Act for indications such as headaches, fatigue, helps detoxify, boosts immune system, aging, increase stamina, kills infectious bacteria, relieves symptoms of PMS in women, and for any other indications other than acute mountain sickness.

Further, our records revealed that you never received premarket clearance for the Hypertec Monocoque, Hypertec Oyster, or for the Hypertec Hybrid which are currently being marketed and distributed.

Because you do not have marketing clearance from FDA, marketing your products is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) because you did not obtain premarket clearance based on information developed by you that shows your device is safe and effective. Your products are misbranded under section 502(o) in that a notice or other information respecting the new intended uses of the device was not provided to the FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to other devices that are legally marketed. Please note that marketing and distribution includes use of the Internet, publications, labeling, and any other source of promotion and advertising materials including fliers, video tapes, brochures, exhibits at trade shows, testimonials from athletes, health care professionals, or alternative medicine proponents, used as labeling from university scientific studies or literature, newspaper articles, etc.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter the steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please address your response to:

Brenda Hayden, RN, MS
Food and Drug Administration
Center for Devices and Radiological Health
Division of Enforcement III
Orthopedic, Physical Medicine & Anesthesiology Devices Branch
2098 Gaither Road
Rockville, Maryland 20850

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does

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not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Brenda Hayden at (301) 594-4659, Extension 150.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: [Redacted]
[Redacted]
[Redacted]