DEPARTMENT OF HEALTH & HUMAN SERVICES M100BN Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED BK

June 20, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-49

Hannelore M. Davis
Owner
Heritage Institute
629 Highway G
Hancock, Wisconsin 54943

Dear Ms. Davis:

During a recent inspection of your firm an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the products listed below which are made and/or marketed by your firm:

1. 10/4 Chakra Charger
2. Bio Shield 2000
3. Rare earth magnets
4. Brassier magnets
5. Shoe magnets
6. Gemini Dual Pacer

Under United States Federal law [the Federal Food, Drug and Cosmetic Act (the Act)], these products are considered to be 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 FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your products for sale. The kind of information you need to submit in order to obtain this clearance is described in the enclosed materials. The FDA will evaluate this information and decide whether your products may be legally marketed.

Because you do not have marketing clearance from FDA, marketing your devices is in violation of the law. In legal terms, the products are adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your devices are adulterated under the Act because you did not obtain pre-market approval based on information developed by you that shows they are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed and because you did not register your establishment and list your products with FDA.

You should also be aware that your products are also misbranded under Section 502(f)(1) of the Act because the directions for use given in the labeling are not adequate to allow a layperson to safely and effectively use the products for their intended purpose. This is because a layperson cannot self-diagnose and self-treat many of the medical conditions for which your devices are intended and because the products are not adequate and effective treatment for these conditions, such as, for example, cancer, HIV, AIDS, tumors and stroke.

You should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issues of pre-market clearance, truthful and adequate labeling, and registration and listing; it does 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 Manufacturer's Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

Your firm also markets and distributes the 4-6 product, Pau D'Arco Tea. Your instructions (labeling) entitled "Instructions for making Pau D'Arco Tea" include therapeutic claims which cause this product to be a drug as stated within Section 201(g) of the Act.

Objectionable claims include the following: "For relief of ulcers take 4 to 6 ounces...," "For leukemia this formula is used by doctors...," "When taking tea for cancer you should...."

Since this drug is a "new drug," as stated in Section 201(p) of the Act, it may not be marketed in the United States without an approved new drug application as directed under Section 505(a) of the Act.

This drug is also misbranded under the Act for two reasons. First, under Section 502(f)(1), the labeling fails to include adequate directions for use for the recommended conditions. Secondly, the labeling suggests that the product is safe and effective for the labeled uses which has never been established, and is false and misleading as stated in Section 502(a) of the Act.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the products, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter of the steps you are taking to correct the violations. 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 corrections. Please direct your response to Compliance Officer Howard Manresa at the address indicated on the letterhead.

If you have more specific questions about how FDA marketing requirements affect your particular devices and drugs, or about the contents of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

In addition, we have reviewed your proposed catalog (labeling) entitled "Unusual Alternatives" which include drug claims for the product Taheebo Tea. Such claims include: "A 'miracle' cure;" "The cure...to certain types of cancer...;" "...is a powerful antibiotic with virus killing properties;" "...help thousands of allergic or chemically sensitive people;" and "...fighting anemia, bronchitis, eczema, external sores, gastritis, ulcers, etc." Inclusion of the disclaimer "...remember in accordance with the FDA regulations we can make no specific claims for results..." does not negate the drug claims made for the product.

Sincerely,

James T. Roberts
Acting Director
Minneapolis District

HEM/cd

Enclosures: Pre-Market Notification Refuse to Accept Policy
How to Submit Pre-market Notification Data