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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 29 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Adel Sheshtawy
American Medical Supply, Inc.
6424 Cunningham Road
Houston, Texas 77041

Re: Chemstrip 10 Reagent Strips for Urinalysis

Dear Mr. Sheshtawy:

This letter is a follow-up to the Food and Drug Administration's (FDA, Agency) inspection of American Medical Supply, Inc. (AMS) from September 30 through October 2, 1997. During the inspection, we collected information that AMS was marketing and distributing in interstate commerce Chemstrip 10 Reagent Strips for Urinalysis, which are manufactured by Boehringer Mannheim, Mannheim Germany, and labeled for sale in Canada. Under the Federal Food, Drug, and Cosmetic 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 Agency is concerned about the distribution of these Canadian-labeled urine test strips. The manufacturers of these products, as evidenced by the labels, intended to sell them only in Canada and not in the United States. Consequently, the manufacturers labeled the products in International System (SI) units that are generally used and recognized in Canada. Because these metric units are not commonly used in the United States, consumers in this country may not be able to appropriately convert and interpret the results generated by the device. The Agency considers the product to be misbranded under 502(f)(1) and 21 CFR 809.10, Labeling for In Vitro Diagnostic products.

You should know that this serious violation 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 product, 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.

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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 of this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again.

There are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter does not address all the obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacture and distribution of medical devices by contacting our Division of Small Manufacturers Assistance at (800) 638-2041 or via the Internet at <http://www.fda.gov>.

If you have any questions about the content of this letter, please feel free to contact Robert G. Brett, Consumer Safety Officer at (301) 594-4588 or fax (301) 594-4636.

Sincerely yours,

Petty W. Collins
for/ Lillian J. Gill
Director
Office of Compliance
Center for Devices
and Radiological Health

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CC:

HFA-224

HFR-140

HFR-SW1580

HFZ-321