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AUG 18 2000

Warning LetterFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850Certified Mail
Return ReceiptDr. Philippe Gradal
General Manager
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Dear Dr. Gradal:

We are writing to you because on April 26 through May 17, 2000, investigators from the Food and Drug Administration (FDA) collected information during an inspection of your facility that revealed a serious regulatory problem involving the products known as, "STA Thrombin Catalog #'s 00611 & 00669, Fibrinogen Control Catalog # 00651, Fibrinogen Assay Catalog # 00869, Fibrinogen Catalog # 00674, F.S. Tests Catalog #'s 00857 & 00887" which are made and marketed by your firm.

Under a United States Federal Law, the Federal Food, Drug, and Cosmetic Act (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.

During the inspection of your facility our investigators were informed that plasma used to manufacture the above listed devices is received from [REDACTED] and has been tested to [REDACTED] standards and that testing is done by a [REDACTED] for HIV and hepatitis. The Code of Federal Regulations (CFR) parts 610.40 and 610.45 respectively require that the plasma used to manufacture the above listed devices must be found nonreactive for Hepatitis and HIV using an FDA approved test kit.

The above listed devices are misbranded in violation of section 502(a) in that the labeling contains statements which represent or suggest that the devices are adequate and effective because the plasma used in their manufacture was tested with an approved method, however they were not tested for Hepatitis and HIV with an FDA approved test kit as required by CFR parts 610.40 and 610.45.

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

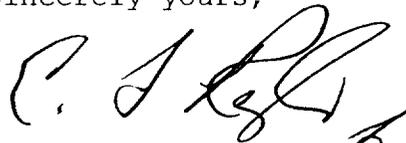
product inventory, obtaining a court injunction against further marketing of the products, or assessing civil money penalties. Also, other Federal Agencies are informed about the warning letters we issue, such as this one, so they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive 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. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to FDA at the above listed address.

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 using a test for hepatitis and HIV not approved by the FDA for plasma used in the manufacture of your devices. 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 questions about the content of this letter, please feel free to contact Robert G. Brett, Consumer Safety Officer at (301) 594-4588.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

*Reviewed
RAB*