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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-05

November 7, 1997

Eduard J. Botz, President
Hyperion, Inc.
14100 S.W. 136th Street
Miami, Florida 33186

Dear Dr. Botz:

We are writing to you because on August 28 through October 1, 1997 FDA Investigator Luz I. Collado collected information that revealed serious regulatory problems involving the Micro Reader III (photometer) and the HyPrep Plus (immunoassay sample preparation station), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to diagnose a medical condition or disease of the body. The law requires that manufacturers of medical devices conform with the Quality System (QS) Regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the Quality System Regulation. These violations include, but are not limited to the following:

- Failure to ensure Device History Records (DHRs) are maintained to demonstrate each device or lot of devices is manufactured in accordance with the Device Master Record (DMR), e.g., rework performed on finished units rejected during final testing is not documented.
- Failure to establish, maintain and document procedures to control product that does not conform to specifications, e.g., there are no records maintained documenting nonconformities related to components or subassemblies found during in-process testing. Material Return Report (MRR) forms are discarded after the components or subassemblies are dispositioned; in-process

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nonconformities documented on the Defective Material Report Record (DMRR) form do not include the determination that an investigation is required, that notification to the responsible person or organization responsible for the nonconformance is made, and that assessments are made to determine the root cause of the defect.

- Failure to establish and maintain procedures for implementing corrective and preventive actions, e.g., corrective actions made as a result of investigations of complaints, in-process or finished product testing that determined defects that adversely affect product quality (complaint #97048).
- Failure to establish, maintain and document procedures for acceptance of incoming components and manufacturing materials, e.g., PCBs received from a vendor, subsequently rejected and returned to the vendor were not adequately documented, nor were the components received from the vendor after rework documented pursuant to established incoming component acceptance procedures. Defects were later found during in-process testing.
- Failure to document revisions made to the Final Testing Procedure e.g., reliability tests for the Micro Reader III were changed from 21 to 11 without documentation verifying or, if appropriate, validating the changes, and the changes were not approved prior to implementation.
- Failure to monitor and document environmental conditions when conducting final testing procedures, e.g., no monitoring of environmental conditions are documented for the Micro Reader III pursuant to established procedure #7790068.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. During the

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inspection the investigator verified corrections to observations 2b, 2c, 3, 7, 8, 11, 12, 13, 16 and 19. Corrections to the remaining observations were promised by March 31, 1998.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the QS Regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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 requirements for the conformance of your devices with the QS Regulation and does not necessarily address other obligations you have under the law. You may obtain general information about all the FDA 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>.

Your response should be directed to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, #120. Orlando, Florida 32809, or if you have more specific

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questions about the GMP requirements and how they affect your particular device, or about the content of this letter, please call (407)648-6823, ext. #264.

Sincerely yours,

A handwritten signature in cursive script that reads "Edward R. Atkins". The signature is written in dark ink and is positioned above the typed name.

Edward R. Atkins
Acting Director
Florida District