



DEPARTMENT OF HEALTH & HUMAN SERVICES

94708d
Food and Drug Administration

May 17, 2004

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-10-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Eli Cohn, CEO
Haemoscope Corporation
5693 West Howard Street
Niles, IL 60714-4011

Dear Dr. Cohn:

Our review of information collected during an inspection of your firm located at the above referenced address on December 2, 3, 4, & 5, 2003, revealed that your firm manufactures Hemostasis Analyzers. This product is a device as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

FDA's inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act [21 U.S.C 351(h)], in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA 483, which listed a number of GMP inspectional observations including, but are not limited to, the following:

1. Failure to follow procedures for finished device acceptance to ensure that each finished devices meets acceptance criteria before the finished devices are released for distribution. [21 CFR 820.80(d)]
2. Failure to ensure that all testing equipment is suitable for its intended use and capable of producing valid results. [21 CFR 820.72]
3. Failure to establish and maintain procedures for implementing corrective and preventive action. Procedures that are required are the verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device. [21 CFR 820.100(a)(4)]

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We have received your letters dated December 22, 2003 and December 31, 2003 responding to the inspectional observations described above. In the letters, you promised to implement the following changes by February 2004:

[REDACTED]

[REDACTED] Your response will not be considered satisfactory until your firm has completed all corrections and provided a final status report to FDA. Further, FDA may need to conduct a re-inspection of your firm to verify that certain changes have been implemented.

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 Form FDA 483 issued at the close 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. You also must promptly initiate permanent corrective and preventative action on your quality system.

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.

You should take prompt action to correct these violations. Failure to promptly correct these violations 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 bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

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Please send your reply to the attention of Matthew J. Sienko, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Sienko at (312) 596-4213.

Sincerely


Richard Harrison
Acting District Director