



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M969N

H/L 35

4/14/97
e/sj

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

June 3, 1997

WL-26-7

Walter L. Binder, Ph.D
President
Inova Diagnostics, Inc.
10451 Roselle Street
San Diego, CA 92121

Dear Dr. Binder:

During an inspection of your manufacturing facility conducted between May 12 and May 14, 1997, our investigators determined that your firm manufactures in vitro diagnostic products. These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (Act).

Our investigation revealed that these 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 manufacturing, packing, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and control written manufacturing specifications and processing procedures to assure that your in vitro diagnostic products conform to their original design or any approved changes to their design [21 CFR 820.100]. For example, our investigation disclosed that your firm does not have sufficient documentation which provides a high degree of assurance that the equipment and processing controls used in the manufacturing of in vitro diagnostic products will consistently produce a product meeting its pre-determined specifications and quality attributes, traditionally termed validation.
2. Failure to conduct investigations, including conclusions and follow-up measures of in vitro diagnostic products which failed to meet their performance specifications [21 CFR 820.162]. For example, our investigation disclosed several incidents where your firm conducted no failure investigations of in vitro diagnostic products which failed to meet their performance specifications. Specifically, our review of your telephone log from 11/18/96 to 5/6/97 disclosed that many oral complaints were not investigated.

3. Failure to ensure your cleaning methods used in the cleaning of your production equipment will sufficiently prevent contamination which could alter the effectiveness of your in vitro diagnostic products [21 CFR 820.60]. For example, our investigation determined that your firm has no documentation which demonstrates that the cleaning method process is valid or data to support that all residues including detergents and solvents from the cleaning process itself have been removed from the equipment or have been reduced to an acceptable level.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. 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 conclusion 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.

We acknowledge that you have submitted to this office a written response concerning our investigator(s) observations noted on the form FDA 483. Although, your response appears to address our concerns, we suggest that your firm submit copies of your written validation protocols and the proposed date of completion of all your corrective measures. A follow-up inspection will be required, to assure that corrections are adequate.

Until it has been determined that corrections are adequate, 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 pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared. Also, no requests for Certificates for Products For Export will be approved.

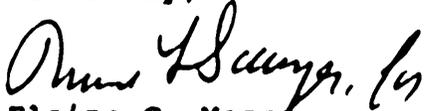
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Such actions include, but is not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of the letter, of the anticipated date that your facility will be ready for reinspection.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92715-2445

Sincerely,



Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Att: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320