



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Tomas Haendler
President
Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763

April 13, 2001

Ref: NYK-2001-59

Dear Mr. Haendler:

During an inspection of your firm on October 16 through November 15, 2000, our investigator collected information regarding Chembio's manufacturing and marketing of test kits for hCG in urine only, and hCG in urine and serum. These pregnancy test kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act").

The hCG Stat Pak Ultra Fast Pregnancy Test Kits (for urine/serum and urine only) and Sure Check™ Pregnancy Test Kits are adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that they are Class III devices under Section 513(f) and do not have approved applications for premarket approval in effect pursuant to Section 515(a) or approved applications for an investigational device exemption under Section 520(g).

The hCG Stat Pak Ultra Fast Pregnancy Test Kits and Sure Check™ Pregnancy Test Kits are misbranded under Section 502(o) of the Act, in that notices or other information respecting the modification to these devices were not provided to the FDA as required by 21 CFR 807.81(a)(3)(i).

Your December 5, 2000 letter responding to the Inspectional Observations issued on November 15, 2000 stated that Chembio's position was that the modifications to the subject devices did not require new pre-market notifications. Our letter of January 24, 2001 informed you that the New York District office had requested CDRH's evaluation of the device modifications. The Center has concluded that the changes are significant modifications.

The hCG Stat Pak and the Sure Check™ Pregnancy Test have been significantly changed in material (critical components) and manufacturing process, which could significantly affect effectiveness. New 510(k)s are required per 21 CFR 807.81(a)(3)(i).

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 its regulations. This letter pertains only to the issue of premarket clearance and does not necessarily address other obligations you have under the law.

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. Also, 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.

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. 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.

Your response should be sent to Laurence D. Daurio, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. W. Thomas', with a long horizontal flourish extending to the right.

Edward W. Thomas
Acting District Director