



DEPARTMENT OF HEALTH & HUMAN SERVICES

m4108n

New York District

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ronald Steinlauf
President
Jerome Stevens Pharmaceuticals, Inc.
60 Da Vinci Drive
Bohemia, New York 11716

September 6, 2000

Ref: NYK-2000-96

Dear Mr. Steinlauf:

During an inspection of your drug manufacturing facility located in Bohemia, New York, conducted between the dates of July 10 and 26, 2000, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). Such deviations cause your drug products, Digoxin Tablets, 0.125 mg. and 0.25 mg., to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. Failure to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products. The processes for the manufacturing of Digoxin Tablets, 0.125 mg. and 0.25 mg. have not been validated [21 CFR 211.110(a)].

The process of manufacturing Digoxin Tablets with a change in the formulation quantity of [REDACTED] that was implemented in 1999 has not been adequately validated.

2. Failure to establish reliable, meaningful and specific test methods for assessing the stability characteristics of Digoxin Tablets [21 CFR 211.166 (a)(3)]. There is no documentation establishing stability indicating test methods.

The above identification of violations and the observations on the FDA-483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

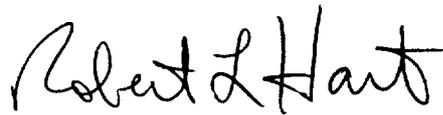
Jerome Stevens Pharmaceuticals, Inc.
page # 2

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of the 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 prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,

A handwritten signature in black ink that reads "Robert L. Hart". The signature is written in a cursive style with a large, prominent initial "R".

Robert L. Hart
Acting District Director