



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

April 26, 1999

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4/24/99
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Mr. Oscar Hubert Campbell
Chief Executive Officer
Seatrace Pharmaceuticals, Inc.
503 Hickman Street
Rainbow City, Alabama 35906

WARNING LETTER - 99-NSV-11

Dear Mr. Campbell:

During an inspection of your manufacturing facility on March 29-April 2, 1999 our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Our inspection revealed the failure to always review and approve the validation of manufacturing processes as well as incomplete validation protocols and a failure to validate the operation of all manufacturing equipment. The inspection also revealed that no annual reviews had been conducted for any of your products and you also failed to have a change control procedure. Other deviations included a failure to always analyze stability samples at the specified test point, a failure to always validate laboratory procedures and a failure to have adequate written component testing procedures.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Until these violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

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

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You should notify this office in writing within fifteen (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 prevent the recurrence of similar violations.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217, Attention: Joseph E. Hayes, Compliance Officer.

Sincerely,



Howard E. Lewis
Acting Director
Nashville District

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