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WARNING LETTER
NWE-22-00W

VIA FEDERAL EXPRESS

February 16, 2000

Colin Stewart
CEO and President
Muro Pharmaceutical, Inc.
890 East Street
Tewksbury, MA 01876

Dear Mr. Stewart:

During an inspection of your drug manufacturing facility located at 890 East Street, Tewksbury, MA on January 8 through 31, 2000 our investigator found significant deviations from the Good Manufacturing Practices for Finished Pharmaceuticals (Title 21 Code of Federal Regulations, Part 211). Such deviations cause drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act). The violations observed during our inspection include, but are not limited to, the following:

1. Failure to have an accurate, sensitive, specific and reproducible test method for the mean content analysis of Volmax® Tablets.
2. Failure to validate the changes you have made to the sample preparation steps for the mean content test method for Volmax® Tablets. For example, you have modified the sample preparation steps for this assay by performing a second [REDACTED] of the sample and also by using [REDACTED] to initially dissolve the tablet. There were no validation studies performed to demonstrate that these changes were effective or did not compromise the final test results.
3. Failure to follow your own SOP, #GENQC-005-03, for the reporting of out of specification data for Volmax® tablets. For example, your SOP states to report and consider all test results, both passing and suspect, in making batch release decisions. On at least two occasions, (11/17/99, lot 10503606 and 4/23/99, lot 10429939A), this was not done, instead failing samples were re-assayed and the original failing values were discarded.

You should take prompt action to correct all of the violations at your firm. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions may include seizure and or injunction under the Federal Food, Drug, and Cosmetic Act.

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

We acknowledge your letter dated February 4, 2000, which was a response to the FDA 483 issued to your firm on January 31, 2000. In that response, you stated a validated method will be developed for the Volmax® mean content assay test method and a development status will be reported to the FDA within 90 days. In your response to this Warning Letter, please advise us of your immediate status with respect to the validation of the Volmax® mean content assay test method and advise us how you plan to assure yourselves in the future that no changes are made to any laboratory methods without the proper validation being completed.

The deficiencies identified in this letter are not intended to be an all-inclusive list of the deficiencies at your facility. As the President, 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 the award of contracts.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675. Extension 113.

Sincerely,



Gail T. Costello

Acting District Director
New England District Office