DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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WARNING LETTER

NWE-07-00W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 16, 1999

Mark C. Puliafico
President
Webco Chemical Corp.
420 West Main Street
Dudley, MA 01571

Dear Mr. Puliafico:

During an inspection of your veterinary drug manufacturing facility located at 420 West Main Street, Dudley, MA, on October 5, 14 and 15, 1999 our investigator found significant deviations from the Good Manufacturing Practices for Finished Pharmaceuticals (Title 21 Code of Federal Regulations, Part 211). Such deviations cause veterinary 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 deviations are as follows:

1. Failure to test each batch of drug product for conformance to final specifications including the identity and strength of each active ingredient, by appropriate laboratory methods, prior to release.

2. Failure to formulate your batch with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient.

3. Failure to have an expiration date on your veterinary drug products, PRE-VAIL and Tandem, that is supported by appropriate stability studies. The limited stability data obtained by your firm for these products have shown that the products are sub-potent after approximately [redacted] This data does not support your labeled two-year expiration date.

4. Failure to have an adequate stability program for your drug products PRE-VAIL and Tandem, that includes (1) the identification of appropriate storage temperatures, (2) a statistical sample size, (3) a reliable, meaningful and specific test method an (4) an adequate number of test batches.

5. Failure to have an adequate master production record for the Prevail and Tandem products that includes (1) a complete list of components, (2) an accurate statement of the measure of each component, (3) a statement of theoretical yield and (4) the finished product specifications for your drug products.

6. Failure to have batch production records that include an accurate reproduction of the appropriate master production record, checked for accuracy, dated and signed.

7. Failure to determine the actual and theoretical yields for each veterinary drug manufactured.

8. Failure to have a written procedure for handling all written and oral complaints regarding your veterinary drug products.

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 these 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 do note that during the inspection you have discontinued the manufacture of these products until the sub-potency issues are resolved. We also acknowledge that you have initiated a recall of both these products. In your response, please advise us of the status of these actions.

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. Additionally, pending Antibiotic Form 6, NDA, ANDA or export approval requests may not be approved until the above violations are corrected.

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,

John Marzilli
District Director
New England District Office