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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

December 21, 2001

WARNING LETTER
CHI-11-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Papineau, President
West Agro, Inc.
11100 N. Congress Ave.
Kansas City, MO 64153

Dear Mr. Papineau:

During an investigation of your veterinary drug manufacturing facility located at 1855 S. Mount Prospect Road, Des Plaines, IL, conducted on September 21-24, 2001, our investigator found significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceutical (CGMP), 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 reported included:

Failure to establish and follow written procedures for cleaning and maintenance of equipment, including utensils used in the manufacture, processing, packing or holding of a drug product [21 CFR 211.67(b)(3)]. The instant inspection revealed that no cleaning validation studies have been performed.

Failure to establish adequate procedures for label reconciliation [21 CFR 211.125(c)]. The inspection showed that labels are neither weighed nor counted, and there is a lack of accountability for labels.

Failure to conduct process validation on at least three lot validation runs [21 CFR 211.110(a)]. The inspection found that the process validation study for Formula 1966-3, product description "New Process," contained only one validation run (7/98), and Formula F-1906-2, product description "Formulation adjustment," contained only one validation run (8/97).

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The above list of deviations and the FDA-483, Inspectional Observations, issued to Michael Russell, Quality Assurance Laboratory Manager, is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. A copy of the FDA-483 is attached.

You should take prompt action to correct the above violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

You should 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, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay, and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Please direct your reply to the attention of Laster B. Shealey, Acting Compliance Officer, at the Chicago District Office.

Sincerely,

\s\
Raymond V. Mlecko
District Director