DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

March 28, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Ref. KAN 2002-005

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

Dear Mr. Papineau:

On February 12-15, 20 and 25, 2002 Food and Drug Administration (FDA) investigators performed an inspection of your drug manufacturing operation at 501 Santa Fe, Kansas City, Missouri 64105. This inspection revealed serious deviations from the current Good Manufacturing Practices, Title 21 Code of Federal Regulations Parts 210 and 211 (21 CFR 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 (the Act) in that the methods used in or the facilities or controls used for their manufacture, processing, packing or holding do not conform to current good manufacturing practices.

Deviations include but are not limited to:

- Records that are required under the regulations must be made readily available for authorized inspection and photocopying or other means of copying. Your firm violated this requirement by refusing to allow access and copying of all records as required by the regulations [21 CFR 211.180(c)]
- There are no written change control procedures that are necessary to assure the production and process controls will be changed in an appropriate method [21 CFR 211.100(a)].
- There is no second person review of laboratory data [21 CFR 211.194(a)(8)].
- There are no Standard Operating Procedures for the inspection of Out of Specification (OOS) results [21 CFR 211.192].
- The written calibration procedures for your laboratory equipment are deficient in that they do not specify calibration intervals or methods [21 CFR 211.160(b)(4)].

- The records and methods for the manufacture of Sodium Iodide USP and Potassium Iodide USP are deficient in that the Master Batch Record and the Batch Production Record do not accurately reflect all the manufacturing steps, there are multiple assay methods noted on the Laboratory Control Sheets without noting the actual method used for the specific analysis, assay methods have not be completely validated and the specifications of the drug products do not conform to the specifications in the U. S. Pharmacopeia (USP) [21 CFR 211.186 and 21 CFR 211.188].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and current regulations. These deviations from the law and implementing regulations were noted on FDA Form 483. The FDA Form 483 was issued to Zaheer Babar, Plant Manager at the close of the inspection. At that time the violations were discussed with Mr. Babar and other members of your firm's management. A copy of the FDA Form 483 is enclosed for your information.

In addition to the noted good manufacturing practices violations, your firm is in violation of Section 301(f) of the Act in that your firm made refusals to permit inspection as authorized by Section 704 of the Act. Our investigators displayed their credentials and issued a written notice, FDA Form 482 that includes Section 704, to your Plant Manager. Section 704(a)(1)(B) identifies the authority the Food and Drug Administration has regarding performing inspections to enforce the Act.

Our investigators were refused required access to the complete manufacturing, processing and complaint records and were not allowed to copy said records. This access and copying is specifically required under the implementing regulations. In addition our investigators were refused access to areas of your facility that were necessary to evaluate equipment and processes. The Food and Drug Administration regards these refusals as serious violations because they hinder our investigators' ability to thoroughly and completely evaluate your firm's ability to make safe and effective drug products.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or injunction. Also other Federal agencies are informed about the Warning Letters issued so they may consider this information when awarding government contracts.

Please inform this office, in writing, within fifteen (15) working days of receipt of this letter of the steps you are taking to correct these deviations. If the corrective actions are going to extend past fifteen days please include in your response a detailed and specific timeline for the completion of your actions.

You should direct your reply to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District

Enclosure

cc: [redacted]