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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 2, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 02

Albert R. Trudeau
President
AJD Laboratories dba Ulmer Pharmacal
1614 Industry Avenue
Park Rapids, Minnesota 56470

Dear Mr. Trudeau:

During our inspection of your drug repackaging facility located in Park Rapids, MN, on August 27-30, 2001, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include, but are not limited to, the following:

1. Failure to document training in current good manufacturing practices for employees in the manufacture of over-the-counter (OTC) drug products (21 CFR 211.25).
2. Failure to establish the reliability of your supplier's certificate of analysis through appropriate validation of their test results at appropriate intervals [21 CFR 211.84 (d)(2)].
3. Failure to follow your written stability program (21 CFR 211.160).
4. Failure to test in-process materials for identity, strength, quality and purity, as appropriate [21 CFR 211.110(c)], in that there is a lack of total organic carbon and conductivity testing of water used in OTC drug products.

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5. Failure to have temperature and humidity controls [21 CFR 211.42(c)(10)(ii)].

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter, of 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 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

CAH/ccl

