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DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

June 5, 1997

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

WARNING LETTER
CHI-31-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David A. Baum, President
Mechanical Servants, Inc.
4615 North Clifton
Chicago, IL 60640

Dear Mr. Baum:

During the inspection of your firm from February 25 to March 4, 1997, Investigator Geraldine Phipps documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). These deviations cause the drug products you repackage to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to document completion of label inspections.
2. Batch records do not include the bottle control code or expiration date.
3. Failure to maintain written procedures for labeling and packaging.

This letter, as well as the Inspectional Observations, FORM FDA 483, dated March 4, 1997 (issued to you), 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 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, NADA, AANDA, or export approval requests may not be approved until the above violations are corrected.

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.

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

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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 frame within which corrections will be completed.

Your reply should be sent to Stephen D. Eich, Compliance Officer.

Sincerely,


Raymond V. Meech
District Director

Enclosure