DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

January 5, 2001

WARNING LETTER

Certified Mail
Return Receipt Requested

Mr. Paul Pritchard, CEO
Toll Compaction Services, Inc.
14 Memorial Drive
Neptune, New Jersey 07753

File No.: 01-NWJ-14

Dear Mr. Pritchard:

An inspection of your firm, located at 12 Memorial Drive, Neptune, NJ, was conducted on October 24, 25, and 31, 2000. During that inspection, our investigator documented serious deficiencies from Current Good Manufacturing Practice (CGMP) Regulations, Title 21 Code of Federal Regulations, Parts 210 & 211. These deficiencies cause pharmaceutical products processed at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigator documented examples related to the product [redacted], however, the deficiencies apply for all active pharmaceutical ingredients and pharmaceutical excipients processed at your facility. Your firm is not operating in a state of control regarding pharmaceutical products as shown by the following:

- No cleaning validation studies were completed to show that the method of cleaning the compacting equipment is sufficient to remove all traces of the previous product, which may be an industrial product. Without documentation that your cleaning procedure is valid for all products, you cannot assure that cross-contamination is not occurring. For example, our investigator observed that prior to the September 2000 campaign of [redacted], the compactor was used to process an industrial product containing Teflon.
- Use logs are not maintained for the equipment used to process pharmaceutical products.
- The compaction process for [redacted] has not been validated. Changes were made to critical control parameters of the process without justification or proper change control, and process and/or cleaning steps were missed or not documented.

There is no assurance that management personnel have the knowledge and experience necessary to operate the pharmaceutical processing operations in accordance with Current Good Manufacturing Practice Regulations due to the following:

- A Quality Control unit did not exist.

- Management personnel did not establish procedures specifically for pharmaceutical products, and in fact, did not know whether some products handled at the facility were regulated by the U.S. Food and Drug Administration or not.
- Management personnel admitted having almost no experience in the pharmaceutical industry or with CGMP Regulations.
- Management personnel reviewed and signed production and cleaning records even though steps were changed without prior approval or not documented as having been completed by the operators. In addition, management allowed employees to complete manufacturing and cleaning records in pencil.

The above list of violations in not considered an all-inclusive list of the violations at your facility. It is your responsibility to ensure that you meet all requirements of the Federal Food, Drug and Cosmetic Act and all applicable federal regulations. Federal agencies are advised of the issuance of all warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

Several of these same observations were brought to your attention via the FDA-483, List of Inspectional Observations, issued to you on November 17, 1998, at the conclusion of our previous inspection. Those observations remain uncorrected in spite of the promises of corrective actions made by you during the inspection and in your letters of December 16, 1998 and June 3, 1998. You should now take prompt action to correct these deficiencies. Failure to correct the deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

On November 21, 2000, we received your correspondence requesting an extension of 90 days to respond to the FDA-483. Upon receipt of this letter, please notify this office within 15 working days regarding the specific steps you have taken to correct the noted violations. This should also include an explanation of each step taken to prevent the recurrence of similar violations. If the corrective actions cannot be completed within 15 working days, state the reason for the delay and the time needed to complete the corrections.

You may send your response to: U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A Della Fave, Compliance Officer.

Sincerely,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director
New Jersey District