



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

10/22/97
470

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-88

September 30, 1997

Scott L. Davidson, President
Star Pharmaceuticals, Inc.
1990 N.W. 44th St.
Pompano Beach, FL 33064

Dear Mr. Davidson:

Inspection of your prescription drug repacking and relabeling operation on August 21-28, 1997, by FDA investigator Philippe L. Noisin, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the repacking of professional samples.

The inspection revealed that these drugs are adulterated within the meaning of section 501(a)(2)(B) of the Act in that the methods used in, or the lack of controls for their repacking do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs as follows:

- 1) Failure to institute or maintain records covering the repacking of drug samples, including:
 - batch control records;
 - component sampling, examination and inventory records;
 - label control records; and
 - records covering review of finished products prior to release for distribution.

2) Failure to have adequate written procedures covering:

receipt, examination, and handling of components, including containers and labels; and,

the preparation and maintenance of master and/or batch production and control records covering appropriate aspects of the repacking operation, including control measures to prevent mixups when more than one operation is taking place.

We have reviewed the records provided to us of corrective actions initiated prior to the conclusion of the inspection, and have several comments:

Your sample record should be clearly marked as a distribution record.

Your return/quarantine record does not indicate the reason for return nor their final disposition.

Your inventory record contains headings such as "VISUAL/PRODUCT *** # OF BOXES CKD ****" but fails to define what these headings refer to.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As president and owner, it is your responsibility to ensure that all drug products you repack and distribute are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections 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 directed to Martin E. Katz, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 265.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, sweeping initial "D".

Douglas D. Tolen
Director, Florida District