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19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Zvi Ryzman  
President  
American International Industries  
2220 Gaspar Avenue  
Los Angeles, CA 90040

W/L 47-00

Dear Mr. Ryzman:

During an inspection of your repackaging facility located at 2220 Gaspar Avenue, Los Angeles, CA, concluded January 25<sup>th</sup>, 2000, an FDA investigator documented deviations from the Current Good Manufacturing Practices (cGMPs) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, (CFR) §211). Those deviations cause all drug products manufactured 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). The violations from 21 CFR §211 include:

1. Failure to establish a quality control unit [21 CFR §211.22].
2. Failure to maintain records in accordance with 21 CFR Subpart J - Records and Reports [21 CFR §211.180 - §211.198]. For example, you do not maintain batch production and control records [211.192] and complaint records [211.198].
3. Failure to establish production and process control procedures designed to assure your drug products have the required identity, strength, quality and purity [21 CFR §211.100(a)]. For example, you have no process validation procedures for the filling and manufacture of any of your OTC drug products nor have you validated the performance of process equipment, you have no validation that your cleaning and sanitation procedures prevent significant cross contamination from multi-use manufacturing process equipment and no procedures outlining production controls, quality controls, and training.
4. Failure to establish and follow adequate written control procedures to validate the performance of manufacturing processes that may be responsible for causing variability in the characteristics of the in process material and the drug product [21 CFR §211.110(a)]. For

example, you have no validated procedures for the control of your filling operations of your OTC drug products.

5. Failure to ensure that all people engaged in the manufacture, processing, packing or holding of a drug product have the education, training and/or experience required to perform their assigned functions [21 CFR §211.25(a)].
6. Failure to establish and follow written procedures detailing the receipt, identification, storage, handling, sampling examination and/or testing of labeling materials [21 CFR §211.122].

During the previous inspection conducted in September of 1999, our investigator provided you information contained in 21 CFR §211.207 that requires establishments involved in manufacturing drug products to register and list their drug products. As defined in §211.207, manufacturing includes, among other things, repackaging of drug products. At the time of the current inspection, you still had not registered as a drug manufacturer nor listed your drug products. Information regarding procedures for registering your establishment and listing your drug products can be found in 21 CFR §211.207 or on our website at <http://www.fda.gov/cder/handbook/druglist.htm>.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your Los Angeles, CA 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, pending Antibiotic Form 6, New Drug Applications, Abbreviated New Drug Applications or export approval requests may not be approved until the above violations are corrected.

We acknowledge that, during the inspection, you committed to stop filling OTC drug products at your facility. However, your firm's inability to make or implement previously promised corrections verified during this inspection, and the inability of your firm to identify which products you manufacture that are OTC drug products, brings into question your firm's ability and commitment to voluntarily comply with the applicable federal laws and regulations, including current Good Manufacturing Practices for Finished Pharmaceuticals. You should be aware that we consider several of the FDA-483 observations (lack of a quality control unit, lack of trained personnel, lack of required records, lack of equipment, process and cleaning qualification/validation and lack of label control and label control procedures) to be highly significant. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

In addition, we offer the following comments:

Our investigator found that, in addition to not maintaining records required in the cGMPs, your firm is not placing manufacturing or lot codes on the finished product containers for your OTC drug products as required by 21 CFR §211.150 and 21 CFR §211.196. The use of lot codes or some other system to easily identify product distribution is necessary to facilitate recall if circumstances require.

Letter to Mr. Ryzman

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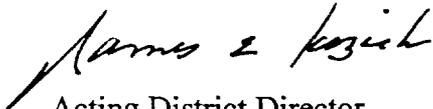
Our investigator examined and found discrepancies in several of the labels your firm currently uses for drug and cosmetic products. During the inspection, you indicated that you intend to continue to use the "old" labels until they are used up and a new batch is printed. We have submitted several labels collected during the inspection to the Center for Drug Evaluation and Research (CDER) for review. We will further advise you when we receive the results of that review, but you should be aware that your continued use of these labels may cause your drug products to be adulterated and/or misbranded.

You should notify this office in writing within fifteen (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 being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your written response should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer  
Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Blvd., Suite 300  
Irvine, CA 92612

Sincerely,



Acting District Director

cc: California Department of Health Services, Food & Drug Branch  
601 N. 7<sup>th</sup> Street  
Sacramento, California 94234-7320  
Attn: Stuart Richardson, Jr., Chief