



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g3490d

1990 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

August 29, 2002

W/L 42-02

Doreen C. Wastchak, President  
Unit Dose Packaging, Inc.  
1818 Grand Ave.  
Phoenix, AZ 85007

Dear Ms. Wastchak

During an inspection of your pharmaceutical manufacturing facility conducted April 23 to 24, 2002, our investigator found significant deviations from the Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). These deviations cause your drug products 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 establish a quality control unit that has responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products, and the authority to review production records to assure that no errors have occurred. [21 CFR 211.22 (a)]. Specifically, there are no employee(s) in the firm designated as a quality control person(s). No activities were observed that would reflect any independent review, test, and/or approval of any aspects of the drug manufacturing operations.
2. Failure to establish, implement, and control laboratory testing procedures for testing and release of final drug product to ensure that products conform to their final specifications, including the identity and strength of each active ingredient, prior to release. [21CFR 211.165(a)]. Specifically, our investigator observed that there was no finished product testing for any of the seventeen (17) different topical anesthetic drug products for necessary chemical or microbiological requirements. Of thirty-one (31) documented batches of drug products produced containing progesterone and/or testosterone, only three batches had finished product testing.

3. Failure to establish procedures to conduct at least one test to verify the identity of each component of a drug product and to use specific identity tests if they exist. [21 CFR 211.84(d)(1)]. Specifically, no identify testing is performed on incoming drug components such as Testosterone, Progesterone, Lidocaine, Tetracaine, and Epinephrine.
4. Failure to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess. [21 CFR 211.100(a)]. Specifically, there are no process records or written process requirements for any of the drug products manufactured, consisting of seventeen (17) types of topical anesthetics and four (4) drug products containing testosterone and/or progesterone. The production batch records do not indicate the manufacturing process of the drug products, including, for example, the equipment utilized, the processing times and temperatures used, calculation of the anticipated production yield, or calculation of the actual amount of finished product.
5. Failure to establish and follow written procedures for the handling of all written and oral complaints regarding drug products [21 CFR 211.198 (a)]. Specifically, complaints from Hawaii via a toll free telephone were acknowledged as received, however there is no procedure to handle these complaints. Follow up on a complaint received on 5/31/99 reporting an "ineffective" product did not include a test of retained product for the potency of the active ingredient.
6. Failure to establish a written testing program to assess the stability characteristics of drug products [21 CFR 211.166 (a)]. Specifically, 21 different drug products are manufactured and sold, and there have been no stability studies completed nor are there any on going stability studies being conducted to show that intended product characteristics are maintained throughout the shelf life of the products. There is no data available to support the current expiration dates labeled on all drug products.
7. Failure to establish a written procedure to calibrate, inspect, and check automated, mechanical, or electronic equipment used to manufacture drug products to assure proper performance. [21 CFR 211.68 (a)]. Specifically, there is no data to demonstrate that production equipment (two mixers, one filler, a water system) has been properly validated (installation qualification, operational qualification, and performance qualification) as acceptable for its intended uses.

In addition, during the inspection of your pharmaceutical manufacturing facility conducted April 23 to 24, 2002, our investigator collected a sample of your product "TAG #45 Topical Analgesic Gel", "ACTIVE INGREDIENTS: Lidocaine 4%, Epinephrine 0.08%  
[REDACTED]". Our laboratory analysis of this sample disclosed that the Lidocaine contained in

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the product was 79.5% of the amount declared on the label. This finding causes this drug product to be adulterated within the meaning of Section 501(c) of the Federal Food, Drug and Cosmetic Act.

Also, the labeling (package insert) for the product "TAG #45 Topical Analgesic Gel" Lidocaine 4%, Epinephrine 0.08%, collected as part of the sample, declares that the product contains 0.08 mg/cc of Epinephrine. The FDA laboratory analysis shows that the product contains 1062.5% of the amount of Epinephrine declared in the package insert. This finding causes this drug product to be misbranded within the meaning of Section 502(a) of the Federal Food, Drug and Cosmetic Act.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. A list of observations (form FDA-483) was issued and discussed with you at the conclusion of the inspection. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations and other applicable regulations. Federal agencies are advised of the issuance of all warning letters about drugs and medical devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations, including your intended corrective actions to address the adulterated and misbranded drug product "TAG #45 Topical Analgesic Gel", "ACTIVE INGREDIENTS: Lidocaine 4%, Epinephrine 0.08%", [REDACTED]. Failure to do so may result in regulatory action without further notice, including product seizure and/or a permanent injunction requiring you to cease manufacture of drug products. You should notify this office 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 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 addressed to:

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

Sincerely,



for Alonza E. Cruse  
District Director