



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g194/d

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 17, 2001

W/L 06-02

William H. Person
Vice President of Marketing
Person & Covey
616 Allen Ave.
Glendale, CA 91201

Dear Mr. Person:

Your firm manufactures a variety of human products, including but not limited to prescription and over-the-counter (OTC) drugs and cosmetics. During an inspection of your manufacturing facility located in Glendale, California, conducted between August 15 and 20, 2001, our investigators found significant deviations from the Current Good Manufacturing Practice (cGMP) regulations for finished pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). Such deviations cause human drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (henceforth the "Act").

Section 501 (a)(2)(B) of the Act states that a drug shall be deemed adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not administered in conformity with cGMP, to assure that such drug meets the quality and purity characteristics which it purports or is represented to possess.

Our inspection found the following deficiencies:

1. Written procedures for production and process control are not followed. For example, you have not performed process validation for Solbar Zinc SPF 38, yet lots have been released for commercial distribution; the process validation protocols for Xerac AC and Drysol lacked provisions for testing final filled containers; and there is no final report or approval of the process validation for prescription antiperspirants. [21 CFR 211.100(b)]
2. Requirements for stability testing of drug products are not being met. For example, you do not have as part of the storage conditions, any documentation that stability samples are maintained at the designated temperature [21 CFR 211.166(a)(2)]; and you have not qualified your accelerated stability chamber [21 CFR 211.166].
3. The procedures for testing of incoming components are deficient in that the written procedure for sampling incoming raw materials does not specify the number of containers to be sampled, or the amount of material to be sampled from each container. [21 CFR 211.84(b)].
4. Written procedures for equipment and maintenance are not adequately established and followed. For example, the existing cleaning and maintenance procedures are not adequately validated to assure the absence of drug, detergent or other residues. [21 CFR 211.67 (a) and (b)]
 - Your cleaning validation report for Hydrocortisone lotion lacks documentation that your cleaning method removes the product from the equipment:
 - a) There is no documentation of the rationale for selecting sampling sites.
 - b) There are no pre-determined acceptance criteria.
 - c) You do not determine the absence of cleaning agent residues.
 - Your firm lacks validation of the cleaning procedures for the piston filler (#PWL-2) and the tube filler (#TF-4)

5. Calibration of instruments is not done at suitable intervals in accordance with an established written program. For example, there are no written procedures for the calibration of scales used in production and in the QC laboratory. [21 CFR 160(b)(4)]
6. Written procedures are lacking to assure that labeling and packaging materials are representatively sampled, and examined or tested upon receipt and before use. For example, there is no written procedure which describes the sampling of incoming labeling to include the number of labels, rolls or containers to be sampled. [21 CFR 211.122(a)]
7. There are no written procedures for the annual evaluation of drug products. [21 CFR 211.80(e)]

The above is not intended to be an all-inclusive list of violations. As a manufacturer of human drugs, you are responsible for assuring that your overall operations and the products you manufacture and distribute are in compliance with the law. Several of the violations noted during this inspection are similar to those previously brought to your attention. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violation may result in regulatory action without further notice, such as seizure and/or injunction. Other Federal Agencies are informed about the Warning Letters issued so they may consider this information when awarding government contracts for drug products.

We have received your September 14, 2001 response to the FDA-483, Inspectional Observations and have the following comments:

While in some very specific circumstances a retrospective process validation can be demonstrated to provide acceptable data to support current processes, the likelihood is very rare. A very critical analysis of data and production conditions is required for acceptable validation of any process or product. Often retrospective reviews of production records do not reveal sufficient data to perform an adequate evaluation.

We acknowledge that you are writing and/or reviewing and approving procedures for the production of drug products. It is important that protocols and procedures incorporate statistically valid and scientifically sound rationale for decisions of what, where, when, why and how products are to be manufactured and released for distribution. This

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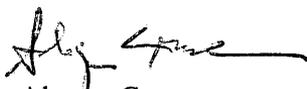
includes processes prior to commercial production including the qualification and/or validation of equipment, processes and testing of components, in-process and finished product. The factors considered in the development and approval of procedures should be documented and maintained for support of decisions made. Your commitment to corrective action is noted and will be incorporated with your response to this letter, however many of your responses lack the specificity we need in order to evaluate the adequacy and appropriateness of your intended actions.

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 the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made. If you have any questions or need clarification regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 798-7739.

Your reply should be directed to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,



Alonza Cruse
District Director