



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

32001d

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 20, 2001

W/L #16-02

Thomas M. Raffy
Owner/President
GAR Laboratories
1844 Massachusetts Ave.
Riverside, CA 92507

Dear Mr. Raffy:

Your firm contract manufactures a variety of human products, including, but not limited to over-the-counter (OTC) drugs and cosmetics. During an inspection of your manufacturing facility located in Riverside, California, conducted between August 14 and 23, 2001, our investigator 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 deficient in that your firm lacks validation of your Reverse Osmosis water system. [21 CFR 211.100]
2. Your firm is not testing each batch of finished drug product for conformance with final specifications prior to release. For example, your firm did not complete finished product testing for your sunscreen product, lot 10606-12, which was shipped on 8/15/01. [21 CFR 211.165(a)]
3. Written procedures for production and process control are not followed. For example, you have not performed process validation for sunscreens, lip balms, analgesic cream and antibacterial handsoap. Additionally you have not completed performance qualification for key pieces of equipment including the autoclave, laminar flow hood, blenders and fillers. [21 CFR 211.100(b)]
4. Laboratory controls, including the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity are inadequate. For example, your firm has not conducted preservative effectiveness studies for your drug products including sunscreens, lip balm, analgesic cream and anti-bacterial hand-soap, even though the "Product Lot Submission" document for each batch includes a one year guarantee against bacterial contaminants. [21 CFR 211.160]
5. Written procedures for equipment cleaning and sanitization are not adequately established and followed. For example, the existing cleaning and sanitization procedures are not adequately validated to assure the absence of drug, detergent or other residues. Additionally, you have not documented the effectiveness of your sanitizing agent. [21 CFR 211.67 (b)]
6. Your firm has failed to maintain complete batch production and control records. For example, your batch records are not complete in that they lack documentation that each significant step such as mixing and heating is completed. [21 CFR 211.188]
7. Master production and control records are inadequate in that they are not prepared, dated and signed by one person and independently checked, dated and signed by a second person. For example, the master production and control record for anti-bacterial liquid soap has a place for "R & D Approved by/ Date" and "QA Approved by/Date," yet there are no signatures or dates on the record, and there is no specimen of the approved labeling attached. [21 CFR 211.186]
8. 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 violations 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 August 29, 2001 response to the FDA-483, Inspectional Observations, and have the following comments:

We acknowledge that you are writing and/or reviewing and approving procedures for the production of drug products. 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. For example, your response to items #2, 11, 12, 13, and 14 is that Mr. Urbayan will be responsible for correcting the deficiency with no other information. Please provide us your anticipated timelines for correction of these items.

Additionally, during the inspection you provided a list of color additives used by your firm that includes D&C Red #19. D&C Red #19 is no longer authorized for use in drug or cosmetic products. Only approved colors may be used in products regulated under the FDC Act.

For your information, while this letter does not comment on the labeling of your products, the labeling for three of your products ([REDACTED] anesthetic, [REDACTED] topical anesthetic, and [REDACTED] topical anesthetic) under review by our Center For Drug Evaluation and Research (CDER). We are requesting that you provide us the actual formulations for these three products to facilitate this label review.

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.

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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