



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-57

June 24, 1998

Ron Rice, President
Tanning Research Labs. Inc.
1190 N. US 1
Ormond Beach, Florida 32174

Dear Mr. Rice:

We are writing to you because on January 28 to February 26, 1998, Investigator Brunilda Torres from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving sunscreen products manufactured and distributed by your firm, which products are human drugs within the meaning of section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these drugs are adulterated within the meaning of section 501(a)(2)(B) of the Act in that they are OTC drugs and the methods used in, or the facilities or controls used for, their manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs specified in Title 21 CFR, Part 211 as follows:

- Failure to document in writing the responsibilities and authority of the Quality Control unit (FDA 483, Item #6).
- Failure to perform and document required product record reviews and analytical test results, or QC unit decisions are overturned without adequate justification and documentation, e.g., production records are not reviewed prior to product release (FDA 483, Item #7); microbiological testing is not completed on water/oil base products (FDA 483, Item #8) or products are shipped prior to the completion of microbiological testing (FDA 483, Item #9); and investigations of batches to meet established standards and written records of investigations are not documented (FDA 483, Item #10).

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- Failure to properly validate finished product test methods (FDA 483, Item #11, 17); failure to adequately validate all manufacturing processes for sunscreen products, e.g., a number of batches were required to be reprocessed or discarded and new product formulations are not validated on a commercial scale under similar manufacturing/laboratory conditions and equipment (FDA 483, Item #1); and failure to validate all manufacturing equipment cleaning procedures (FDA 483, Item #21).
- Failure to document all manufacturing operations at the time of performance (FDA 483, Item #2); failure to follow established manufacturing instructions (FDA 483, Item #3), e.g., the investigator observed instances when designated manufacturing steps were completed and/or documented prior to the next listed manufacturing step; failure to have written procedures for reprocessing batches not meeting specifications (FDA 483, Item #5), e.g., the manufacturing department commonly makes decisions to reprocess batches without input from QA, R&D, or QC; and there is no documentation recording these decisions.
- Failure to adequately monitor environmental factors affecting products on stability (FDA 483, Item #18), and to include portions of annual production batches on study to ensure stability parameters are continuous (FDA 483, Item #19), e.g., relative humidity is not monitored and temperature is only monitored on a weekly basis with a thermometer that is not accurately calibrated (FDA 483, Item #18).
- Failure to always follow manufacturing instructions as specified in the production records, e.g., persons with the responsibility for verifying that manufacturing steps are completed and documented properly, fail to detect deviations (FDA 483, Item #3).
- Failure to maintain manufacturing equipment in good state of repair, e.g., holding tanks are dented, holding tanks are not properly covered, rough welds in holding tanks and pipes, transfer pipes and discharge valves are not self-draining and long sections of transfer pipes are not able to be cleaned or sanitized because sections are welded together (FDA 483, Item #20).
- Failure to investigate all complaints and an annual review of complaints is not conducted as required by your own procedures (FDA 483, Items #32 and 33).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. FDA 483 items not specifically listed above are also considered to be serious violations from the regulations and must also be corrected for complete compliance to be achieved. It remains your responsibility to ensure adherence to each requirement of the Act and regulations.

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We have completed our review of your firm's response signed by Robert L. Dowdell, Technical Director, dated March 25, 1998 to the Inspectional Observations (FDA 483) issued to Jack E. Surette Jr., Vice President Marketing and Product Development on February 26, 1998. While our response does not address all of your firm's responses to the FDA 483, we have addressed those items listed above and have the following comments:

FDA 483, Item #1 - Your firm's response fails to address validation for existing products that were never properly validated. Your response also fails to provide any procedures covering the validation, the sampling plans or analyses that you intend to conduct to assure validation is complete.

FDA 483, Items #2 and 5 - Your firm's responses appear adequate. Please provide copies of documentation for our review and files.

FDA 483, Item #3 - Your firm's response is inadequate because you fail to provide evidence of the training conducted, documentation of employees completing the training, and who is responsible for conducting the training. Your firm's response also fails to provide documentation of manufacturing revisions including supervisory review, and the documentation covering QA review and their findings, i.e., when deviations are found, how are they investigated, corrected, and the preventive actions taken.

FDA 483, Item #6 - Your firm's response states that a SOP is currently being written, however, it does not state when you expect the SOP will be completed and implemented. Please provide a copy of the SOP when finalized for our review and files.

FDA 483, Item #7 - Your firm's response appears to be adequate. Please provide a copy of a recent example of this operation for our review and files.

FDA 483, Item #8 - Your firm's response appears adequate and will be verified at the next scheduled inspection of your facility.

FDA 483, Item #9 - Your firm's response is inadequate because it fails to state how release operations will be handled, who is responsible and how releases will be documented and controlled. Please provide copies of all documentation that has been developed and implemented since this inspection.

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FDA 483, Item #10 - Your firm's response appears adequate, however, it fails to address a required written procedure, fails to provide a copy of an existing QC Incident Report, and what controls will be established to ensure product is properly released and documented.

FDA 483, Item #11 - Your firm's response appears to be adequate and will be verified at the next scheduled inspection of your facility.

FDA 483, Items #17 & 18 - Your firm's responses appear adequate and will be verified at the next scheduled inspection at your facility. **FDA 483, Item #17** - Please provide a copy of your contractor's validation protocol for our review and files.

FDA 483, Item #20 - Your firm's responses are inadequate because they do not address the listed observation and there is no documentation that details the procedures or new operations that were instituted to effect corrective action.

FDA 483, Item #21 - Your firm's response fails to provide a copy of the procedures that you intend to implement, copies of documents used record results, and on what basis cleaning and/or sanitation will take place. Your firm's response also fails to state how this process will be validated and documented. Please provide copies of any protocols or documentation covering this aspect of your validation.

FDA 483, Items #32 and 33 - Your firm's responses are inadequate because there is no evidence that you have begun to investigate complaints that lack unused portions of product or copies of any documentation covering investigations that may have been conducted. Also you fail to provide documentation that an annual review has been conducted or will be in the near future.

You should take prompt action to correct all of the violations including those previously listed on the FDA 483. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and 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 corrections will be completed.

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Your response should be sent to the Food and Drug Administration, Florida District Office,
555 Winderley Place, Suite #200, Maitland, Florida 32751, Attention: Martin E. Katz,
Compliance Officer.

Sincerely,

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

Douglas D. Tolen
Director, Orlando District