



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

60 8th Street, N.E.  
Atlanta, Georgia 30309

November 13, 2000

VIA FEDERAL EXPRESS

Mike D. Whitaker  
President  
Unique Laboratories, Inc.  
1475 Highway 76  
Suite #3  
Chatsworth, Georgia 30705

WARNING LETTER  
(01-ATL-7)

Dear Mr. Whitaker:

An inspection of your drug manufacturing facility located at 1000 Jackson Lake Road in Chatsworth, Georgia, was conducted on October 17 & 25, 2000, by Investigator Vicky C. Stoakes. The inspection revealed several significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMPs), as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your drug products, such as skin protectants, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

You could provide no assurance that your products met the identity, purity, and quality claims made on the labeling. Each batch of drug product must have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of the active ingredient, prior to release. You could provide no analytical data for the active ingredient in any lots manufactured by your firm. In fact your firm does not have equipment capable of conducting assays of the active ingredient.

You have failed to conduct any evaluation of your products to determine the need for microbiological testing of these products. No microbiological testing has been conducted on any of your drug products. You have failed to assure that all production records are properly reviewed by quality control prior to product release. Unique Skin lot #100200-A failed to meet specification for viscosity and pH, but was released for distribution under three production codes. There was no indication on the batch record that these out-of-specification results had been noted.

You have failed to establish appropriate written procedures for production and process control designed to assure that your drug products have the identity, strength, quality, and purity they purport or are represented to possess. The available procedures were incomplete and in various stages of preparation. A responsible reviewing official had approved none of the procedures and the available procedures did not cover the majority of operations conducted by your firm.

One significant omission was the lack of procedures to address the reconciliation of labeling. No records were available for the number of labels received, issued, or returned to stock. The failure to adequately control labeling issuance resulted in your use of rejected labels on Skin Guardian product on June 28 and October 11. This material was subsequently released for distribution. This labeling had been rejected in response to our observations during the previous inspection.

You have failed to establish and prepare batch production and control records for each batch of drug product produced to include complete information relating to the production and control of each batch. Batch records lacked documentation of critical steps such as mixing times and temperatures. Batch records also failed to document the actual quantity of raw materials utilized, lacked specifications for acceptable deviations between actual and theoretical yield, and did not include copies of labeling used.

You have failed to appropriately validate the manufacturing processes currently utilized for any of your drug products. You could not provide documented evidence which established a high degree of assurance that the manufacturing processes were effective and could consistently produce a product meeting its predetermined specifications and quality attributes. You have failed to establish the adequacy of the significant pieces of production equipment currently in use. You have failed to establish the adequacy of the cleaning procedures currently utilized.

You have failed to ensure that each person engaged in the manufacture, processing, packing, or holding of your drug products, and each person responsible for supervision of these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug products have the quality and purity that they purport or are represented to possess. This training must not only be in the particular operations that the employee performs but also include current good manufacturing practice as it relates to the employee's functions. This lack of adequate training included production, quality control, and management personnel.

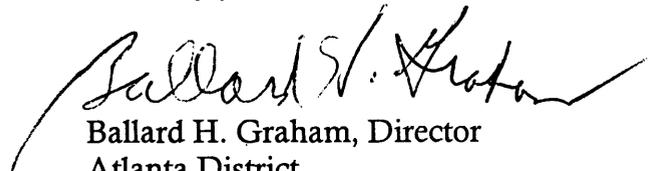
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Many of the above deviations were included on the Inspectional Observations (FDA 483) which was issued to and discussed with you at the conclusion of the inspection. The specific violations noted in this letter and in the FDA 483 could be symptomatic of underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to seizure and/or injunction.

Please notify this office in writing within fifteen (15) 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 identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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 response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Of additional concern is the fact that you failed to appropriately respond to our previous Warning Letter in regards to Clear Shield and Skin Guardian products. You were notified in January of this year that these products, as previously labeled, were unapproved new drugs. You continued to manufacture and distribute these products utilizing this labeling after receipt of our letter. We do note that you have attempted to retrieve these products from distribution channels as a result of the most recent inspection. We also note that you stated that you would [REDACTED] until you can come into compliance.

Sincerely yours,



Ballard H. Graham, Director  
Atlanta District