



Memorandum

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-30

May 16, 2003

Griscom Bettle, III, President
CBC Research, Inc.
1715 Independence Blvd.
Ste. B7
Sarasota, Florida 34232

Dear Mr. Bettle:

On November 26 through December 3, 2002, the Food and Drug Administration (FDA) conducted an inspection of your over-the-counter (OTC) pharmaceutical and cosmetic skin care products manufacturing facility located at 1715 Independence Blvd., Sarasota, Florida. During the inspection, FDA Investigator Virginia L. Meeks documented significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals [Title 21, Code of Federal Regulations (CFR), Parts 210 and 211]. These deviations cause the products manufactured by your firm to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). These deviations include, but are not limited to, the following:

- 1) Failure to have adequate written procedures for production and process controls designed to assure that drug products have the identity, strength, quality and purity they purport to possess [211.100(a)].

For example, adequate procedures are not established for the validation of manufacturing processes.

- 2) Failure to withhold from use each lot of components, drug product, containers, and closures until the lot has been sampled, tested, examined, and released by the quality control unit [211.84(a) and 211.84(d)].

For example, the reliability of the Certificates of Analyses obtained from suppliers has not been determined. Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality. It is not acceptable for unapproved materials to be used in production until the Quality Control Unit (QCU) releases the materials.

- 3) Failure to have appropriate design, adequate size, and suitable location for the equipment used in the manufacture, processing, packing, or holding of a drug product to facilitate operations for its intended use and for its cleaning and maintenance [211.63].

For example, adequate Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) have not been performed on critical equipment used in the manufacture of drug product.

- 4) Failure to have adequate sampling and testing of in-process materials and drug products [211.110(a) and 211.110(b)].

For example, your firm only monitors acidity levels during the manufacturing of each batch. Other characteristics, such as batch uniformity and homogeneity, are not addressed.

- 5) Failure to implement a testing program designed to assess the stability characteristics of drug products [211.166(a)].

For example, there is no written testing program designed to assess the stability characteristics of drug products. The proposed corrective action plan did not include any documentation to support the current expiration dates being used or the suitability of the new stability protocol that is being designed by Microconsult, Inc.

Your products, Burn Stuff and Cut Stuff, which are drugs as defined in section 201(g) of the Act, are shipped unlabeled from your manufacturing site to Unit Packaging Co., Inc., Cedar Grove, NJ, for repackaging and labeling without any written labeling agreement. While it is permissible under certain circumstances to ship unlabeled drug products to another firm for repackaging and labeling, such shipment may only be done legally if you have a written labeling agreement with the other firm and comply with all the provisions as described in 21 CFR 201.150. Because the unlabeled products are shipped in interstate commerce without such a written labeling agreement, they are misbranded under sections 502(b)(2), 502(f)(1) and 502(e) in that the labeling fails to bear a net contents statement, adequate directions for use, and an ingredients statement, respectively.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It remains your responsibility to ensure adherence to all requirements of the Act and regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We acknowledge receipt of your response to the FDA-483 dated January 8, 2003. We consider your response to be inadequate because it does not completely address all the observations on the FDA-483.

Please notify this office within fifteen (15) working days of receipt of this letter, of the further steps you have taken to correct these violations and to prevent the recurrence of similar violations. Please include in your response the product specifications for both the "Cut Stuff" and "Burn Stuff" that CPM Laboratories has developed for these products, and the records developed by your firm that demonstrate these specifications are part of the products release criteria. If corrective action cannot be completed within fifteen (15) working days, please state the reason for the delay and the specific timeframe(s) within which the corrections will be completed.

Your reply should be directed to Martin E. Katz, Compliance Officer, U. S. Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,


for Emma R. Singleton
Director, Florida District