



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Atlanta District Office

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

December 11, 2002

**VIA FEDERAL EXPRESS**

Hank Picken  
President  
Beaumont Products, Inc.  
1560 Big Shanty Drive  
Kennesaw, Georgia 30144

**WARNING LETTER**  
(02-ATL-07)

Dear Mr. Picken:

Investigators Penny H. McCarver and D. Ross Spears of this office conducted an inspection of your drug manufacturing facility on July 16, 2002 through July 26, 2002. During that inspection, information and labeling were obtained for *Citrus II<sup>®</sup> Protective Skin Cream*, *CitruScent<sup>®</sup> Protective Skin Cream*, and *CITRUS MAGIC<sup>®</sup> LIQUID HAND SOAP*. These products are currently manufactured and marketed by your firm for over-the-counter (OTC) distribution.

The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, Office of Compliance reviewed the labeling for the above referenced products. The immediate container label and accompanying promotional labeling for *Citrus II<sup>®</sup> Protective Skin Cream* bear statements such as, "Protective Skin Cream," and "Invisible Barrier Protects Skin from Harsh Chemicals, Latex Gloves . . . and More." The immediate container label and accompanying promotional labeling for *CitruScent<sup>®</sup> Protective Skin Cream* bear statements such as, "Protective Skin Cream," and "Invisible Barrier Protects Skin from Harsh Chemicals: Perms • Dyes . . . Acrylic Nail Catalysts . . . Peroxide • Acetone . . . and much more." The immediate container label for *CITRUS MAGIC<sup>®</sup> LIQUID HAND SOAP* bears statements, such as "CITRUS MAGIC LIQUID HAND SOAP with Grapefruit Seed Extract," which is prominently featured on the label, and "With Citrus Magic you can safely remove germs . . . ." These statements represent and suggest that *Citrus II<sup>®</sup> Protective Skin Cream* and *CitruScent<sup>®</sup> Protective Skin Cream* are intended to form an impervious barrier on the skin to prevent adverse effects caused by contact with hazardous substances and skin irritants, and that *CITRUS MAGIC<sup>®</sup> LIQUID HAND SOAP* is useful in preventing diseases caused by microorganisms. Based on these intended disease-prevention uses, these products are "drugs" as defined by section 201(g)(1)(B) of the Act.

We are not aware of any substantial scientific evidence that the products described above are generally recognized by scientific experts as safe and effective for their respective labeled uses. As formulated and labeled, these products are not being considered in any of the rulemakings under FDA's OTC Drug Review. Therefore, *Citrus II*<sup>®</sup> *Protective Skin Cream*, *CitruScent*<sup>®</sup> *Protective Skin Cream*, and *CITRUS MAGIC*<sup>®</sup> *LIQUID HAND SOAP* are "new drugs" as defined by section 201(p) of the Act. Because neither of these products is the subject of an FDA-approved new drug application (NDA), the current marketing of them in the United States by your firm violates section 505(a) of the Act.

In addition, these drug products are misbranded under sections 502(e) of the Act, because their respective labels do not identify any active ingredient(s). We acknowledge receipt of a letter dated August 26, 2002, cosigned by Howard F. Morin and Dennis C. Vincent of your firm to Ms. McCarver of this office. In that letter Messrs. Morin and Vincent advise that the immediate container labels for *Citrus II*<sup>®</sup> *Protective Skin Cream* and *CitruScent*<sup>®</sup> *Protective Skin Cream* have been revised to remove all skin barrier representations and that stocks of all previous labels and marketing materials for these two products have been destroyed. These remedial actions are an adequate response to the "new drug" and misbranding violations described above for *Citrus II*<sup>®</sup> *Protective Skin Cream* and *CitruScent*<sup>®</sup> *Protective Skin Cream* and these actions are commendable. However, due to the serious nature of the violations described above and the fact that they were neither discussed during the July 2002 inspection nor in the August 26, 2002 letter, regarding *CITRUS MAGIC*<sup>®</sup> *LIQUID HAND SOAP*, and the absence of a commitment from your firm concerning the disposition of existing inventories of these products bearing violative labeling, we believe that a formal notice of these violations through this Warning Letter is appropriate.

FDA is presently evaluating the safety and efficacy of skin protectants under the agency's OTC Drug Review and a tentative final monograph (TFM) for such products was published in the Federal Register (FR) of February 15, 1983 (48 FR 6820). Skin barriers are not included in this rulemaking. OTC antiseptic cleansers are also being evaluated under the Review and TFMs for such products were published in the Federal Register of January 6, 1978 (43 FR 1210) and June 17, 1994 (59 FR 31402). Grapefruit seed extract is not covered by this rulemaking. The TFM for OTC skin protectants and the 1978 TFM for antiseptic cleansers may be available from your local library, while the 1994 TFM for antiseptic cleansers is available on the World Wide Web at [http://www.access.gpo.gov/su\\_docs/](http://www.access.gpo.gov/su_docs/). Pending a final monograph or other final rule, FDA does not object to the marketing of products that meet both the formulation and labeling requirements described in these proposed rules and comply with existing regulations affecting these products. Such marketing, however, is subject to the risk that a final monograph or rule may require reformulation and/or relabeling or FDA approval through the "new drug" procedures of the Act (section 505).

If *CITRUS MAGIC*<sup>®</sup> *LIQUID HAND SOAP* was intended and labeled solely for use as a deodorant soap with claims like "removes the germs that cause odor," we would not object to the marketing of such a product at this time. It would be regulated as a "cosmetic" under the Act and subject to all of the requirements for "cosmetic" products. Please note, however, in the TFM for OTC first aid antiseptic drug products, which published in the Federal Register of July 22, 1991

(56 FR 33644) under the OTC Drug Review, FDA proposed that products bearing claims like “removes the germs that cause odor” are “drugs” under section 201(g) of the Act (56 FR 33644 at 33648-33649). If that proposal becomes effective, products intended for this use would have to comply with all pertinent final monographs. Compliance with final monographs may require that *CITRUS MAGIC® LIQUID HAND SOAP* be reformulated and/or relabeled or approved through the NDA procedures to be legally marketed in the United States.

The inspection referenced above also revealed numerous significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMPs) under Title 21 of the Code of Federal Regulations, Part 211 (21 CFR 211). These CGMP deviations, described below, cause your drug products, which include antibacterial cleansers, hand sanitizers, and skin protectant creams, to be adulterated under section 501(a)(2)(B) of the Act.

You have failed to conduct appropriate laboratory determinations to assure conformance to final specifications for each batch of drug product. This testing must include the identity and strength of each active ingredient, prior to release of the finished batch of drug product [21 CFR 211.165(a)]. You could provide no analytical data for the active ingredient in any batch of drug product manufactured and released at your firm. In fact, your firm does not have equipment capable of conducting assays of the active ingredients. The only testing conducted on finished product is a fill weight check and labeling examination. You have failed to develop formalized approved procedures that would establish what the final specifications actually are for any of your drug products.

You have failed to appropriately validate the manufacturing processes currently utilized for your drug products [21 CFR 211.100]. You could not provide documented evidence which established a high degree of assurance that all of your manufacturing processes were effective and could consistently produce a product meeting its predetermined specifications and quality attributes. No process validation data had been generated for any of your drug products or processes.

You have failed to assure that each lot of components used in your drug products meet appropriate specifications for purity, strength and quality prior to use [21 CFR 211.84]. There were no written approved procedures establishing raw material specifications. Incoming drug components are not subjected to any identity testing prior to acceptance. No testing is performed on any incoming component used in the formulation of your drug products. Incoming raw materials are accepted for use based solely on the presence of a Certificate of Analysis. You have never established the reliability of any supplier's analysis through validation of the test results. Your SOP BP-009 states that QA will inspect all incoming raw materials except chemicals in accordance with established inspection criteria. No such inspection criteria have been established however.

You have failed to conduct any evaluation of your components to determine the need for microbiological testing [21 CFR 211.113(a)]. You have failed to establish that your water, a predominant drug ingredient, is of appropriate chemical and microbiological quality at any point of use. You have performed no chemical or microbiological testing of this water system. The

water is supplied by Cobb County and little effort is made to purify the component prior to use. You have failed to initiate any validation of the water system to ensure that it meets any established specifications for purity and quality. In addition, no specifications have been established for this critical component as discussed above [21 CFR 211.84].

You have failed to establish and maintain appropriate batch production and control records for each batch of drug product, to include complete information relating to the production of each batch [21 CFR 211.188(a)and(b)]. The available manufacturing records failed to include specific instructions for critical mixing and filling procedures such as mix times, sample weights, and sampling instructions. Batch Tickets for Citrus II Hand Sanitizing Lotion manufactured between June and August 2001 had no manufacturing instructions. Records reviewed included unapproved formulation changes in the manufacture of this Hand Sanitizing Lotion. It was not clear which version was used to manufacture Lot HS031. Our investigators were informed that the wrong Batch Ticket had been used to manufacture Lot HS032. The production records also failed to have significant production steps, such as addition of raw materials, verified by a second responsible person. Label verification and reconciliation records were not included in the available batch records. The equipment used in the drug manufacturing process was also not identified in the records.

You have failed to establish formalized written testing procedures designed to assess the stability characteristics of any of your drug products [21 CFR 211.166(a) and (b)]. Our investigators were told that all drug products had been assigned a three year expiration date. This expiry date appears to have been arbitrarily chosen, as no stability data was available to support the time period selected. A review of released lots of Antibacterial Hand Soap and Protective Cream during the inspection found them to lack an expiration date. The presence of this date is to be verified prior to release. The Batch Tickets for these lots indicate that no expiration date had been assigned for these two products.

You have failed to establish and validate written procedures for the cleaning of all equipment used in the manufacture of your drug products [21 CFR 211.67(a) and (b)]. No written procedures have been established to address the cleaning or sanitization of your water system. In fact, no cleaning or sanitization has been conducted of the system currently in place. The available cleaning procedures lacked sufficient detail to assure that production equipment is sufficiently cleaned prior to use. No validation has been conducted to assure that previous products and cleaning agents have been adequately removed from equipment prior to reuse. This is of particular concern in that pharmaceutical products and other non-pharmaceutical products such as insect repellants are manufactured in common equipment such as mixers and filling lines. No records are available to document if appropriate cleaning occurs prior to drug production. No equipment usage or cleaning log is maintained making it difficult, if not impossible, to determine the succession of products manufactured in equipment at your firm [21 CFR 211.67(c)].

You have failed to establish separate or defined areas, or other control systems as necessary, to prevent contamination or mix-ups during all aspects of handling, storage and use of raw materials, in process goods, and finished products [21 CFR 211.42(b) and (c)]. No defined storage areas have been established for components or finished products regardless of status.

Chemical raw materials were noted to be stored throughout all areas of the manufacturing and warehouse areas. The manufacturing and warehouse areas were not maintained in a clean, sanitary manner. You have failed to establish adequate control procedures, in that materials are not always labeled as to their status.

You have failed to establish and document the responsibilities and procedures applicable to the quality control unit. The quality control unit must have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. You have failed to establish written procedures which adequately address the responsibilities and procedures applicable to your quality control unit [21 CFR 211.22].

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs so that they may take this information into account when considering the award of contracts. In addition, any pending New Drug Applications, Abbreviated New Drug Applications, or export certificate requests submitted by your firm may not be approved until the above violations are corrected. The CGMP deviations, described above, were included on the Inspectional Observations (FDA 483) form, which was issued to and discussed with Howard Morin, Vice President of Operations, at the conclusion of the inspection. A copy of the FDA 483 is enclosed for your review. We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receiving this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations described above. It should also include an explanation of each step being taken to prevent recurrence of similar violations. Please enclose with your response copies of any revised labeling, promotional materials, product inserts, and Internet Web pages for the products described above. We acknowledge that, during the inspection, our investigators were advised that domestic distribution of your skin protectant products would cease, pending compliance with all pertinent requirements under the Act, but no corrective action was described regarding violative products currently under your control or in distribution channels. Your response should address these issues. Your response to this Warning Letter should also describe any steps taken to ensure that your cosmetic products have not been affected by the CGMP deviations affecting your manufacture of drug products. The use of adulterated components in these products is also a significant concern to FDA.

We acknowledge receipt of responses from your firm dated August 26, September 30, and November 27, 2002. Although corrective actions have been promised we still have significant concerns about your operation. You continue to manufacture drug products utilizing manufacturing processes that have not been validated. You have failed to validate your recently installed water system. In addition numerous procedures need to be written or revised to address

the problems noted on the FDA 483. You may reference these responses if you feel they adequately address a violation discussed above.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. If you wish to discuss this letter or our continuing concerns with your facility, you should contact Mr. Campbell at (404) 253-1280.

Sincerely yours,

A handwritten signature in cursive script that reads "Dawn L. Todd-Murrell".

Dawn L. Todd-Murrell, Acting Director  
Atlanta District

Enclosure