



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127 JEH

February 11, 2002

VIA FEDERAL EXPRESS

Mr. Larry DeFrance  
President/CEO  
Cumberland Swan, Inc.  
One Swan Drive  
Smyrna, TN 37167

**Warning Letter No. 02-NSV-13**

Dear Mr. DeFrance:

During an inspection of your facility on December 4, 2001 – January 11, 2002, our investigator documented violations of the Current Good Manufacturing Practice Regulations (CGMPs), Title 21, Code of Federal Regulations, Part 211. These violations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed a failure to validate cleaning procedures, routine release of and failure to investigate out-of-specification test results for a mouthwash product, failure to conduct statistical analysis for products on long term stability, failure to perform stability testing on all manufactured products, failure of a second individual to confirm the weight of a drug component and failure to accurately identify components used in drug manufacturing.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Current Good Manufacturing Practice Regulations. Until these violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

We would like to point out that despite your written commitment (your letters dated 01-21-2000, 04-03-2000, 04-25-2000, 07-28-2000 and 01-26-2001) to correct deficiencies noted during the previous inspection of your firm conducted between December 6, 1999 and January 7, 2000, this current inspection reveals 30 separate CGMP deviations, including 6 of which were identified during the Dec/Jan 2000 inspection. We acknowledge the explanations in your response dated January 24, 2002; however, we feel that these errors could, and should, have been avoided by diligent quality control management.

We have reviewed the response to our investigator's observations noted on the Form FDA 483 and have the following comments:

1. Observation No. 14 – This item must include a reasonable timeframe for conducting antimicrobial effectiveness testing on stability samples as well as reasonable timeframes for the completion of the statistical analysis validation for the long-term stability data. A "long-term goal" is not acceptable as a timeframe.
2. Observation No. 15 – This item must include a reasonable timeframe in which samples from all manufactured products will be put on long-term stability.

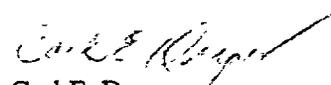
3. Observation No. 10 – The formula for Blue Mint Antiseptic Mouthwash was changed on June 11, 2001 with samples placed on long-term stability; but, no samples were placed on accelerated stability. The product continued to be given a 2-year expiry date with approximately ● lots manufactured with the new formula. Data will not be available to support the 2-year expiry date until June 11, 2002. Notwithstanding your contention that the formula change was minor, involving only flavor, a review of documents revealed that the flavor contained active ingredients and the percentage of the active ingredients changed in the new formula.
4. In regard to the 14 observations on the Form FDA 483 concerning the production of Magnesium Citrate Oral Solution:
  - a. These observations reveal a serious concern by the Food and Drug Administration (FDA) in regard to your production employees, production management and quality control personnel in following Current Good Manufacturing Practices.
  - b. The corrections indicated by the response will have to be evaluated at a future inspection.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure and/or injunction.

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. Your reply should be sent to the U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217, attention: Joseph E. Hayes, Compliance Officer.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

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Enclosure:

21 CFR, Part 211