DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
95951d

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

December 5, 2005

2006-DAL-WL-09

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Carlton E. Turner, Ph.D., D.Sc.
President and CEO
Carrington Laboratories, Inc.
2001 Walnut Hill Lane
Irving, Texas 75038

Dear Dr. Turner:

On August 24-30, 2005, an investigator from the Dallas District Office of the Food and Drug Administration (FDA) inspected your firm, located at 2001 Walnut Hill Lane, Irving, Texas. During this inspection, samples were collected for analytical testing and for a determination regarding compliance with the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act on FDA's web site at www.fda.gov.

Our analysis found the presence of the microorganism *Burkholderia cepacia* in lots 0505851 and 0505832 of your Medline Alcohol-Free Mouthwash (4 fl. oz.) products. These products, therefore, were adulterated within the meaning of section 601(a) of the Act [21 U.S.C. § 361(a)], in that they bore or contained a poisonous or deleterious substance which may have rendered them injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual.

Additionally, we found that your Medline Alcohol-Free Mouthwash products (2 fl. oz. and 4 fl. oz.) were adulterated within the meaning of section 601(c) of the Act [21 U.S.C. § 361(c)], in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Your employees failed to follow appropriate procedures for sanitizing the equipment filling hoses, which, according to your investigation, were found to be contaminated with *B. cepacia*. At least 10 lots of finished product were distributed that were later determined to have been contaminated with *B. cepacia*.

Some of these mouthwash products were also misbranded within the meaning of section 602(a) of the Act [21 U.S.C. § 362(a)], because their labels failed to declare a color additive ingredient properly. Review of your production records for these products reveals that they are formulated with FD&C Blue No. 1. Title 21, *Code of Federal Regulations* (CFR), Section 701.3 requires that this color additive be declared as an ingredient as "FD&C Blue No. 1" or "Blue 1." However, the labels for some of your products simply listed "Blue Dye" as an ingredient.

The above observations are not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the Act. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We note that you initiated a recall of all codes of your Medline Alcohol-Free Mouthwash. We also note that you submitted a response to the Inspection Observations Form FDA-483 issued to you at the end of this inspection, which did not address Observation 2. We received another response letter dated November 17, 2005. In this letter, Observation 2 is still not addressed and no additional information was provided in response to Observation 3.

Please notify this office in writing within 15 working days of receipt of this letter, the additional 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. Please include documentation of any additional investigation conducted to determine the underlying cause of the contamination of the equipment or your products.

Your response should be sent to Sherrie L. Krolczyk, Compliance Officer at the above letterhead address. If you have questions regarding any issue in this letter, please contact Ms. Krolczyk, at 214/253-5312.

Sincerely,

Michael A. Chappell
Dallas District Director