



May 4, 2001

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER

SJN-01-011

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Rueben Mark
Chairman & CEO
Colgate Palmolive Company
300 Park Avenue
New York, NY 10022

Dear Mr. Mark:

From March 29, 2001 to April 6, 2001, our office conducted a GMP inspection of your fluoride toothpaste manufacturing facility, Colgate Palmolive PR, Inc., located at Rd. 3 Km 144.7, Guayama, PR 00785. The inspection revealed significant violations of the regulations covering the Current Good Manufacturing Practices for finished pharmaceutical as defined by Title 21, Code of Federal regulations, Part 210 & 211 (21 CFR 211) and Part 355. These violations cause your drug product, Colgate fluoride toothpaste, to be adulterated within the meaning of Section 501 (a)(2)(b) of the Federal Food, Drug and Cosmetic Act (the Act). The violations include:

Quality System

1. Failure to reject Batch CDC-9-0692 of Great Regular Flavor Colgate Toothpaste (GRF) even though you knew that the abrasive material Tetrasodium Pyrophosphate (TSPP) was not added to the GRF during its formulation. This finding was documented in your investigation 99-13. The abrasive ingredient is necessary for dentifrice products to facilitate mechanical removal of dental plaque, debris, and stain from tooth surfaces as required by 21CFR 355.10. This batch was released for market distribution and its label indicated that it contained this abrasive component.
2. Your investigation also revealed that an excess of 6 additional pounds of sodium monofluorophosphate (MFP), the active ingredient of the toothpaste, were added during the manufacturing process of batch CDC-9-0692. You got OOS results for the TSF test during in process testing. The assay values for this batch were outside the

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required specifications for TSF of 850 ppm to 1,150 ppm as required by 21CFR355.10. This batch was released for market distribution.

3. Failure to have adequate controls to ensure that your Quality Control Unit will approve or reject all components, drug product containers, closures, in process materials, packaging material, labeling, and drug products as required by 21CFR 211.22. For example:

-A laboratory analyst released batch CDC-9-0692 of GRT Colgate Toothpaste for shipping to another Colgate facility, even though it was still pending laboratory results. At the time of this inspection, any analyst could release products. According to your SOP 20-010-08, the releases for products that are still in quarantine have to be approved by the Quality Control Unit. Even though this batch had OOS results for the TSF test, it was released for market distribution.

-Investigation report 99-15 indicates that 6 lots of monofluorophosphate (MFP), the active ingredient of the toothpaste, were approved and used to manufacture toothpaste without all the required laboratory tests in 1999. A laboratory analyst, without the involvement of the QC Unit, approved the lots. Your investigation failed to identify 6 additional MFP lots that were used for production without being tested. The tests were not conducted because the analyst decided that these tests were not necessary.

4. Failure to analyze each component of the toothpaste for purity, strength, and quality as required by 21CFR 211.84. Your change control procedure is also deficient, because changes could be done without QC Unit involvement and the deviation from written procedures was not recorded and justified as per 21CFR 211.100. For example:

-From April 1998 through July 1999, twelve (12) lots of monofluorophosphate (MFP) were approved for use in manufacturing without the following required tests: Soluble Fluoride (%SF) and Fluoride (%MFP). These analyses are important because you do not certify your suppliers. One laboratory analyst made the decision of not doing full testing of this raw material without notifying the QC Unit.

Neither this letter nor the list of inspectional observations is meant to be an all-inclusive list of deviations at your facility. It is your responsibility to ensure that your facility is in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act and all applicable regulations and standards. 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.

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Please notify the San Juan District office in writing, within 15 working days of receipt of this letter, of your responses to the violations identified in this letter. Corrective actions addressed in your letter may be referenced in your response to this letter as appropriate. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or Injunction.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901-3223, Attention: Margarita Santiago, Acting Compliance Officer.

Sincerely,


Mildred R. Barber
District Director

Cc: Ms. Melanie Horneck
Colgate Palmolive, Inc.
Road # 31, No. 100
Juncos, PR 00777-3802

Mr. Luis Pina Pañellas
Colgate Palmolive PR, Inc.
P.O. Box 540
Guayama, PR 00785-0540