DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-231/S-053

Colgate-Palmolive Company
Attention: Boyce (Mack) M. Morrison Jr., Ph.D.
Associate Director of Regulatory Affairs, North America
909 River Road
P.O. Box 1343
Piscataway, NJ 08855-1343

Dear Dr. Morrison:

Please refer to your supplemental new drug application dated October 30, 2006, received October 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Colgate Total® Toothpaste (0.24% sodium fluoride and 0.30% triclosan dentifrice paste).

We acknowledge receipt of your submissions dated May 10, August 13, and October 11, 2007. Your submission of May 10, 2007 constituted a complete response to our April 30, 2007 action letter.

This supplement provides for a change in formulation of Colgate Total® Advanced Clean Plus Whitening Toothpaste including a replacement of the silica and a change in three inactive ingredients.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 13, 2007.

We remind you to remove the word "NEW!" from the principal display panel (PDP) after 180 days of marketing.

We remind you that labeling for any additional sizes of this variant may be submitted in an annual report if the only change to the approved labeling is the net contents statement. Any other proposed changes in the labeling for additional sizes of the same product must be submitted in a prior approval supplement.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Andrea Segal

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