



NDA 20-231/S-046

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 December 14, 2005, received December 15, 2005, 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 9 and July 27, 2006.

Your submission of May 9, 2006 constituted a complete response to our April 12, 2006 action letter.

This supplement provides for a new variant of Colgate Total® Toothpaste, Colgate Total Advanced Clean plus Whitening Toothpaste.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the draft labeling (carton, tube and sachet labeling submitted July 27, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-231/S-046.**" Approval of this submission by FDA is not required before the labeling is used.

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

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, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

*{See appended electronic signature page}*

Joel Schiffenbauer, M.D.  
Deputy 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/

-----  
Joel Schiffenbauer  
9/15/2006 02:40:33 PM