



NDA 20-231/S-047

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 July 17, 2006, received July 20, 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 submission dated January 8, 2007. We also acknowledge receipt of your commitment regarding this supplement dated March 20, 2007, in which you agreed to remove the word "Improved" from the labeling at the time of next printing, or 180 days, whichever is sooner.

This supplement provides for a change in formula of the Colgate Total® Clean Mint Toothpaste variant by replacing a portion of the silica abrasive with high cleaning silica. The proposed reformulated product will replace the currently marketed Clean Mint variant.

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 (1.0 oz. sachet, 4.2 oz., 6.0 oz. and 7.8 oz. tube and carton labeling submitted July 17, 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-047.**" Approval of this submission by FDA is not required before the labeling is used.

We have the following additional recommendation for implementation at the time of the next

printing:

The 6.0 oz. carton should be revised to increase the separation between the drug and cosmetic claims under the promotional statement “As soon as you finish brushing, bacteria start to build up on your teeth and cause:”.

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
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/s/

Joel Schiffenbauer
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