DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-231/S-055

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 May 9, 2007, received May 10, 2007, 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).

This supplement provides for a change in formulation of Colgate Total® Clean Mint Toothpaste to replace [redacted] with [redacted] a new [redacted]

We have completed our review of this supplemental new drug application. 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 (0.1 oz. sachet, and 0.75 oz., 4.2 oz., 6.0 oz., and 7.8 oz. tube and carton labeling submitted May 9, 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-055**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we have the following comment:

> In the future, if the in vitro release data for fluoride or triclosan exceeds that of already approved products, you will need to provide additional information supporting the safety of the product.

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 (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}

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

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