DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-231/S-042

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

Dear Dr. Morrison:

Please refer to your supplemental new drug application dated March 21, 2005, received March 22, 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 July 28 and September 22, 2005.

Your submission of September 22, 2005 constituted a complete response to our July 21, 2005 action letter.

This supplement provides for an alternate manufacturing site for six Colgate Total® Toothpaste variants (Paste, Mint Fresh Stripe, Plus Whitening Gel, Plus Whitening Paste, Advanced Fresh, and Clean Mint).

Your correspondence dated October 7, 2005 withdrew the Total Clean Mint variant from this supplement.

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 for the following variants - Paste, Mint Fresh Stripe, Plus Whitening Gel, Plus Whitening Paste, and Advanced Fresh.

The final printed labeling (FPL) must be identical to the draft labeling (package labeling submitted March 21, 2005), 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-042**." Approval of this submission by FDA is not required before the labeling is used.

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}

Andrea Leonard Segal, M.D.
Acting 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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