DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-231/S-023

Colgate-Palmolive Company
Attention: Richard K. Bourne, Ph.D.
Director, Regulatory Affairs
909 River Road
P.O. Box 1343
Piscataway, NJ 08855-1343

Dear Dr. Bourne:

Please refer to your supplemental new drug application dated October 31, 2001, received November 2, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Colgate Total® Toothpaste, Colgate Total® Fresh Stripe Toothpaste, and Colgate Total® Plus Whitening Toothpaste (0.24% sodium fluoride and 0.30% triclosan).

This Changes Being Effected supplemental new drug application provides for a 0.10 oz. sachet for each of the three variants of Colgate Total® Toothpaste listed above.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container and carton labels submitted October 31, 2001) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated FPL for approved supplement NDA 20-231/S-023. Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a Dear Health Care Professional letter) is issued to physicians and others responsible for patient care, 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

Please submit one market package of the drug product when it is available.

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, R.Ph., project manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Linda Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Linda Katz

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