DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-231/S-028

Colgate-Palmolive Company
Attention: Eugénie C. Acosta
Manager, Regulatory Affairs
909 River Road
P.O. Box 1343
Piscataway, NJ 08855-1343

Dear Ms. Acosta:

Please refer to your supplemental new drug application dated October 3, 2002, received October 4, 2002, 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).

We acknowledge receipt of your submissions dated January 22 and 28, February 12, April 28, and September 4 and 12, 2003. Your September 12, 2003, submission constituted a complete response to our August 29, 2003, action letter.

This supplemental new drug application provides for a new formulation to be marketed as Colgate Total Advanced Fresh 2 in 1 Toothpaste and Mouthwash Freshness.

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

The final printed labeling (FPL) must be identical to the submitted draft labeling (4.6 oz and 5.8 oz. bottle labels submitted September 12, 2003). Please submit the FPL electronically 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, in no case 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-028." Approval of this submission by FDA is not required before the labeling is used.

In addition, we recommend for all product sizes, that the statement "Call toll-free" be revised to appear in regular (unbolded) type under the "Questions or comments?" section of the labeling.

We remind you to remove the word "NEW" on 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) 827-2301.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
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/

Charles Ganley

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