DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-231/S-037

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 April 27, 2004, received April 28, 2004, 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 submission dated October 12, 2004. Your submission of October 12, 2004, constituted a complete response to our August 26, 2004, action letter.

This supplemental new drug application provides for a new Clean Mint flavor for Colgate Total® Toothpaste.

We have completed our review of this supplemental 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 submitted draft labeling (tube and carton labels submitted October 12, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 15 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-037." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove word "New" from the statement "New Great Taste!" 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 set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Project Manager, at (301) 827-2276.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, 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/

Curtis Rosebraugh
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