DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20231/S-058

SUPPLEMENT APPROVAL

Colgate-Palmolive Company
Attention: Charles P. Ireland, B.A., M.B.A.
Director of Regulatory Affairs, North America
909 River Road
PO Box 1343
Piscataway, NJ 08855-1343

Dear Mr. Ireland:

Please refer to your Supplemental New Drug Application (sNDA) dated July 30, 2007, received July 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Colgate Total® (sodium fluoride 0.24% / triclosan 0.30%) Toothpaste.

We acknowledge receipt of your amendments dated November 5, and December 5, 2007, April 20, June 8, July 9, August 11, August 13, August 14, and December 17, 2009, January 21, April 12, April 30 and May 14, 2010.

The December 17, 2009, submission constituted a complete response to our August 21, 2009, action letter.

This "Prior Approval" supplemental new drug application provides for a new variant, Colgate Total® Advanced Fresh Gel Toothpaste with two new flavors at a total concentration of (b) (4) silica (b) (4) and a change in carton graphics including a change in net weight content for two sizes (7.8 oz. and 6.0 oz. to 7.6 oz. and 5.8 oz., respectively).

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We remind you to submit updated reports regarding triclosan antimicrobial resistance in your NDA annual reports.

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed 7.6 oz., 5.8 oz., and 4.2 oz. carton labels submitted November 5, 2007, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 7.6 oz., 5.8 oz., and 4.2 oz. immediate containers (tubes), we request that you submit these immediate container labels as part of the FPL for this

supplement to maintain a record of the complete labeling being approved as part of this supplement.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for Approved NDA 020231/S-058**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag "NEW" from the labels six months after introduction into the marketplace.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jessica M. Diaz, Regulatory Project Manager, at (301) 796-4908.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton Labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20231	SUPPL-58	COLGATE PALMOLIVE	COLGATE TOTAL(0.3% TRICLOSAN, 0.243% SOD

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
09/15/2010