DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020231/S-072
NDA 020231/S-073

SUPPLEMENT APPROVAL

Colgate-Palmolive Company
Attention: Cynthia Andersen
Manager, Regulatory Affairs, USA
909 River Road, P.O. Box 1343
Piscataway, NJ 08855-1343

Dear Ms. Andersen:

Please refer to your Supplemental New Drug Application (sNDA) 020231/S-072, dated December 10, 2012, received December 12, 2012, and sNDA 020231/S-073, dated December 19, 2013, received December 20, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Colgate Total® (sodium fluoride and triclosan) Advanced Toothpaste, 0.24%/0.3%.

We acknowledge receipt of your amendments for sNDA 020231/S072, dated January 31 and May 20, 2014; and for sNDA 020231/S-073, dated January 31 and May 20, 2014.

SUPPLEMENT 072

The December 9, 2013, submission for sNDA 20231/S-072 constituted a complete response to our June 5, 2013 action letter.

This Prior Approval supplemental new drug application provides for change of the variant descriptor from the approved Colgate Total® Advanced Whitening and Cleaning to Colgate Total® Advanced Clean Between, and for a new 0.75 oz. package size.

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

LABELING

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 labeling: 0.75 oz. and 5.8 oz. (representative of the 4.0 oz. and 7.6 oz.) immediate container (tube) and carton labels submitted on May 20, 2014. The 5.8 oz. label will serve as a representative package size. Any changes approved for the 5.8 oz. label must be incorporated onto the labels of the 4.0 oz. and 7.6 oz. package sizes, which are identical to the 5.8 oz. label with the exception of the net weight. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

SUPPLEMENT 073

This Prior Approval supplemental new drug application provides for a new variant descriptor from the approved Colgate Total® Toothpaste to Colgate Total® Daily Repair, and for a new 0.75 oz. package size.

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

LABELING

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 labeling: 0.75 oz. and 5.8 oz. (representative of the 4.0 oz. and 7.6 oz.) immediate container (tube) and carton labels submitted on May 20, 2014. The 5.8 oz. label is intended to serve as a representative package size. Any changes approved for the 5.8 oz. label must be incorporated onto the labels of the 4.0 oz. and 7.6 oz. package sizes, which are identical to the 5.8 oz. label with the exception of the net weight. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling for these supplements 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 20231/S-072 and NDA 20231/S-073**." Approval of these submissions by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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 Celia Peacock, Regulatory Project Manager, at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
06/11/2014