



NDA 20-231/S-026

Colgate-Palmolive Company  
Attention: Eugenie 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 June 6, 2002, received June 7, 2002, 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 change in the tube metric diameter for the 0.75 oz., 6.0 oz. and 4.2 oz. packages and changes in the labeling content for the 6 oz. size.

We have completed our 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 (tube and carton labels for the 6 oz. package size submitted June 6, 2001). We note that you submitted draft tube and carton labeling for the 6 oz. size only. If you wish to implement these changes, you must also submit FPL for the 0.75 oz. and 4.2 oz. sizes for all three products. The 0.75 oz. and 4.2 oz. labeling should be identical in content to the approved 6.0 oz. labeling.

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-026." Approval of this submission by FDA is not required before the labeling is used.

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  
12/6/02 04:13:41 PM