DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-028/S-015

APPROVAL LETTER

3M ESPE Dental Products
Attention: Shari L. Myszka, Pharm.D.
Regulatory Affairs Specialist
3M Center, 275-2W-08
St. Paul, MN 55144-1000

Dear Ms. Myszka:

Please refer to your Supplemental New Drug Application (sNDA) dated September 9, 2010, received September 14, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Peridex® (chlorhexidine gluconate) Solution, 0.12%.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the change in address of the analytical testing laboratory ((b) (4)) used for testing and releasing of the drug product, Peridex® Oral Rinse. The previous location of the facility was (b) (4) The facility was relocated to (b) (4)

We have completed our review of this supplemental new drug application. This supplement is approved.

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 Jeannie David, Regulatory Project Manager, at (301) 796-4247.

Sincerely,

{See appended electronic signature page}

Thomas Oliver, Ph.D.
Branch Chief
Branch VI
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
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/

THOMAS F OLIVER
09/28/2010