# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**73695**

# APPROVAL LETTER

ANDA 73-695

Colgate-Palmolive Company
Attention: Paul J. Okarma, Ph.D.
P.O. Box 1343
909 River Road
Piscataway, NJ 08855-1343

JAN 14 1994

Dear Sir:

This is in reference to your abbreviated new drug application dated December 13, 1990, submitted pursuant to Section 505(j) of the Food, Drug, and Cosmetic Act, for PerioGard® (Chlorhexidine Gluconate Oral Rinse, 0.12%).

Reference is also made to your amendment dated November 22, 1993.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined that your PerioGard® (Chlorhexidine Gluconate Oral Rinse, 0.12%) is bioequivalent to that of the listed drug Peridex® (Chlorhexidine Gluconate Oral Rinse, 0.12%) manufactured by Proctor and Gamble.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and

Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/ 1/14/94

Roger L. Williams, M.D.
Associate Director for Science and Medical Affairs
Center for Drug Evaluation and Research

cc: ANDA 73-695
Division File
FIELD COPY
HFD-600/Reading File
HFD-82

Endorsements

HFD-625/SSherken/11/30/93 Extended Annual Leave Stephen Sherken 12/23/93
HFD-625/MSmela/12/01/93 M Smela 12/16/93
HFD-625/VVashio/12/14/93 Vashio 12/14/93
HFD-613/CHoppes C. Hoppes 12/14/93
Joan Arcuri for R. Patel 12/21/93

APPROVAL