NDA 20-774 May 15, 1998

Target Research Associates, Inc.
Attention: Robert J. McCormack, Ph.D.
1801 East Second Street
Scotch Plains, NJ 07076

Dear Dr. McCormack:

Please refer to your new drug application dated December 20, 1996, received December 20, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PerioChip (chlorhexidine gluconate) 2.5 mg.

We also refer you to your approvable letter dated November 25, 1997.

We acknowledge receipt of your resubmission dated December 5, 1997, received December 17, 1997. The User Fee goal date for this application is June 17, 1998.

We also acknowledge receipt of your submissions dated April 29, August 19, November 18, December 5, 9, and 10, 1997; January 13 (2), 21, March 12, and April 17 and 28, 1998.

This new drug application provides for use of the drug product as an adjunct to scaling and root planing procedures for reduction of pocket depth in patients with adult periodontitis.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed approved labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed approved labeling text. Marketing the product with FPL that is not identical to this approved labeling may render the product misbranded and an unapproved new drug.

Please submit 20 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 "FINAL PRINTED LABELING" for approved NDA 20-774. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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, please contact Roy Blay, Project Manager, at (301) 827-2020.

Sincerely yours,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**ENCLOSURE**