DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-774/S-007

Dexcel Pharma Technologies, Ltd.
c/o To the Point, LLC
Attention: Mary Lou Zett, Ph.D., CQE
President
PMB 316
16 Mount Bethel Road
Warren, NJ 07059-5604

Dear Dr. Zett:

Please refer to your supplemental new drug application dated June 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PerioChip® (chlorhexidine gluconate) 2.5 mg.

We acknowledge receipt of your submissions dated December 29, 2003 and January 16, 2004.

Your submission of January 16, 2004, constituted a complete response to our December 18, 2003, action letter.

This supplemental new drug application provides for revisions to carton labeling.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) (carton) submitted on January 16, 2004.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Jonathan Wilkin
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