DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-774/S-003

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

Dear Dr. Zett:

Please refer to your supplemental new drug application dated August 27, 1999, received August 30, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PerioChip® (chlorhexidine) 2.5 mg.

We acknowledge receipt of your submissions dated August 10 and November 7, 2000, April 3 (2), September 19, and October 31, 2001, and February 20, and November 7 (3 facsimiles), 12 (facsimile) and 13 (facsimile), 2002.

This supplemental new drug application provides for adding the Geriatric Use subsection to the Precautions section of the Package Insert. In addition, two sentences have been added to the General subsection of the Precautions section of the label to strengthen the clinician's awareness of potential adverse events and to reinforce the need for care in selecting and monitoring patients for whom PerioChip is suitable.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels).

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 20-774/S-003." 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 reporting requirements for an approved NDA (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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