DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21451/S-005 **SUPPLEMENT APPROVAL**

Dentsply Pharmaceutical, Inc.
1301 Smile Way
York, PA 17404

Attention: Denise Spellman
Pharmaceutical RA Manager

Dear Ms. Spellman:

Please refer to your Supplemental New Drug Application (sNDA), dated October 13, 2009, received October 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Oraqix® (lidocaine and prilocaine periodontal gel) 2.5%/2.5%

We acknowledge receipt of your submissions dated November 3, 2009, and March 19, 2010.

This "Changes Being Effected" supplemental new drug application provides for the revised labeling for the Oraqix® Dispenser unit carton and Directions for Use to enhance the safe use by the dental practitioner, and modifications to the Dispenser carton labeling to harmonize labeling and to comply with regulatory requirements for marketing in the multiple countries in which Oraqix® is approved.

CONTENT OF LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below.

In the Directions For Use, section 1.6, the following underlined section of the sentence is missing and must be added:

The blunt-tip end of the applicator may be bent to improve access to the periodontal pockets, using the cap.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed, the enclosed labeling (text for the Oraqix Dispenser Directions For Use).

These revisions are terms of the NDA approval. For administrative purposes, please designate this submission, "SPL for approved NDA 21451/S-005.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21451/S-005**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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, contact Diana Walker, Ph.D., Regulatory Health Project Manager, at (301) 796-4029.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Directions For Use
Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21451	SUPPL-5	DENTSPLY PHARMACEUTICAL	ORAQIX

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

/s/

BOB A RAPPAPORT
04/13/2010