DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20612/S-011 **SUPPLEMENT APPROVAL**

Teikoku Pharma USA, Inc.
1718 Ringwood Avenue
San Jose, CA 95131

Attention: Margie Nemcik-Cruz, MA
Regulatory Consultant

Dear Ms. Nemcik-Cruz:

Please refer to your Supplemental New Drug Application (sNDA), dated March 2, 2010, received March 4, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lidoderm® (Lidocaine Patch 5%)

This "Changes Being Effected" supplemental new drug application provides for the following revised **PRECAUTIONS** section of the Package Insert. A new subsection, **External Heat Sources**, has been added.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on March 4, 2010.

CONTENT OF LABELING

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20612/S-011**."

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

Enclosure:
Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20612	SUPPL-11	TEIKOKU PHARMA USA INC	LIDODERM

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