DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-612/S-008

Teikoku Pharma USA, Inc.
1718 Ringwood Avenue
San Jose, CA 95131-1711

Attention: Gail Sheirbon
Sr. Administrator, Regulatory Affairs

Dear Ms. Sheirbon:

Please refer to your supplemental new drug application dated October 20, 2006, received October 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lidoderm (lidocaine 5%) patch.

We acknowledge receipt of your submission dated April 7, 2006.

This "Changes Being Effected" supplemental new drug application provides for changes to the "HANDLING AND DISPOSAL" and "ADVERSE REACTIONS" sections of the package insert and changes to the envelope and carton text.

We have completed our review of this application, as amended and it 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, and submitted labeling (immediate container [envelope] and carton labels submitted April 7, 2006).

We remind you that in your April 7, 2006 submission you agreed to implement the changes approved in this supplement at the next printing of the labeling for this product.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-612/S-008**." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

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

Enclosure