DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-353/s-019

Stat-Trade, Inc.
63 West Trenton Avenue
Morrisville, PA 19067

Attention: Donald P. Cox, PhD
Director, Regulatory Affairs

Dear Dr. Cox:

Please refer to your supplemental new drug application dated April 12, 2007, received April 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Naprelan® (naproxen sodium).

We acknowledge receipt of your submission dated May 11, 2007, received May 15, 2007 containing the final printed labeling in the SPL format.

This "Changes Being Effected" supplemental new drug application provides for revisions to the NSAID Medication Guide table "NSAID medicines that need a prescription" to include the class labeling changes for all NSAID medications has been approved.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 15, 2007.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, call Sharon Turner-Rinehardt, Regulatory Project Manager, at (301) 796-2254.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Bob Rappaport

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