DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-353/S-023 **APPROVAL LETTER**

Stat-Trade, Inc.
c/o Victory Pharma, Inc
11682 El Camino Real, Suite 250
San Diego, CA 92130

Attention: Chris Santos, MS
Associate Director, Regulatory and Quality Affairs

Dear Mr. Santos:

Please refer to your supplemental new drug application dated November 14, 2008, received November 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Naprelan® (naproxen sodium).

We acknowledge receipt of your submission dated June 4, 2009.

This "Changes Being Effected in 30 days" supplemental new drug application provides for for an updated tablet compression tooling to improve appearance, update to container/closure system, and addition of the 750 mg strength Tablets to the package insert.

We completed our review of this application, 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 and, immediate container labels submitted in on November 14, 2008 and in your email dated June 4, 2009.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-353/S-023**." 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
Suite 12B05
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, call Sharon Turner-Rinehardt, Regulatory Health Project Manager, at (301) 796-2254.

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

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

/s/

Sharon Hertz
7/8/2009 06:19:04 PM
Signing for Bob Rappaport, M.D.