DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-320/S-063

Stat-Trade, Inc.
Attention: Donald Cox, PhD.
Vice President, Regulatory Affairs
3000 Cabot Blvd. W.
Suite 200
Langhorne, PA 19047

Dear Dr. Cox:

Please refer to your supplemental new drug application dated July 2, 2008, received July 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MYAMBUTOL® (ethambutol hydrochloride) Tablets, 100mg and 400mg.

This submission responds to the Supplement Request letter issued by the Division on January 19, 2007.

This "Changes Being Effected" supplemental new drug application provides for the following revision to the package insert (added text is underlined).

In the **ADVERSE REACTIONS** section, the last paragraph, third sentence has been revised as follows:

> Other adverse reactions reported include: hypersensitivity, anaphylactic/anaphylactoid reactions, dermatitis, erythema multiforme, pruritus, and joint pain; anorexia, nausea, vomiting, gastrointestinal upset and abdominal pain; fever, malaise, headache, and dizziness; mental confusion, disorientation, and possible hallucinations; thrombocytopenia, leucopenia, and neutropenia. Numbness and tingling of the extremities due to peripheral neuritis have been reported.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the package insert submitted on July 2, 2008.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call June Germain, Regulatory Health Project Manager, at (301) 796-4024.

Sincerely,

{See appended electronic signature page}
Renata Albrecht, MD
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Renata Albrecht

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