DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-085/S-055/S-052

Clonmel Healthcare Ltd.
c/o STADA Pharmaceuticals Inc.
Attention: Dolores M. Turnage
5 Cedar Brook Drive
Cranbury, NJ 08512

Dear Ms. Turnage:

Please refer to your supplemental new drug application dated June 11, 2003, received June 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methotrexate Sodium Tablets.

We acknowledge receipt of your submission dated October 2, 2003.

Regarding NDA 8-085/S-052, your submission of June 11, 2003 constituted a complete response to our December 20, 2002 action letter.

We note that your May 29, 1992 submission concerning final labeling (FA) for supplemental application S-039 supersedes this application. Therefore, it will be retained in our files.

These supplemental applications propose to change the blister packer, analytical testing site, and labeling.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text with the provision that the Spanish version is an accurate translation of the English patient package insert.

The final printed labeling (FPL) must be identical to the agreed-upon enclosed labeling text for the package insert, and patient package insert. The FPL for the immediate container and carton must be identical to the June 11, 2003 submitted labeling with the provision that the Lot No. and Exp. date are included as provided in your October 2, 2003 communication.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 8-085/S-055/S-052." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
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 Paul Zimmerman, Project Manager, at (301) 594-5775.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling text

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

/s/

John Johnson
10/24/03 09:46:42 AM
John R Johnson for Richard Pazdur