



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 8-085/S-058

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 March 17, 2006, received March 20, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methotrexate Sodium Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for two additional strengths of 17.5 mg and 20 mg dose packs.

We completed our review of this application. This application 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 submitted labeling (package insert, immediate container and carton labels submitted March 17, 2006), with provision, as noted in our October 24, 2003 letter, that the Lot No. and Exp. date are included as provided in your October 2, 2003 communication.

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 8-085/S058.**" Approval of this submission by FDA is not required before the labeling is used.

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, Regulatory Project Manager, at (301) 796-1489.

Sincerely,

*{See appended electronic signature page}*

Robert Justice, M.D.  
Acting Director  
Division of Drug Oncology Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Robert Justice  
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