



ANDAs 87-844/S-025 (10 mg)
87-845/S-025 (25 mg)
87-846/S-026 (50 mg)

Mallinckrodt Inc.
Attention: Celeste M. Reisch
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Madam:

This is in reference to your supplemental new drug applications dated August 27, 2007, submitted pursuant to 21 CFR 314.70(c)(6)(Supplement - Changes Being Effected) regarding your abbreviated new drug applications for Tofranil® (Imipramine Hydrochloride Tablets, USP).

The supplemental applications provide for revisions to the package insert labeling and medication guide as requested in the August 7, 2007 correspondence from the Agency.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs

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

/s/

Lillie Golson
9/27/2007 04:04:25 PM
Lillie Golson for Wm. Peter Rickman