DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-906/S-030

Mallinckrodt Inc.
Attention: Russell Reed
Labeling Manager
675 McDonnell Blvd., P.O. Box 5840
St. Louis, MO 63134-0840

Dear Mr. Reed:

Please refer to your supplemental new drug application dated September 10, received September 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anafranil (clomipramine hydrochloride) 25 mg, 50 mg, and 75 mg Capsules.

We additionally refer to an Agency approvable letter dated May 11, 2004 for the above supplemental application.

We acknowledge receipt of your submission dated June 17, 2004, providing for a response to our May 11, 2004, Agency letter.

This supplemental new drug application proposes the following revisions to product labeling:

1. Revision of labeling to add a **Geriatric Use** section under **PRECAUTIONS** to comply with 21 CFR 201.57.

2. Revision to the **CLINICAL PHARMACOLOGY** section to incorporate the results of a Phase 4 study entitled "Multiple Ascending Dose Proportionality of Anafranil in Obsessive-Compulsive Disorder (OCD) Patients" as requested in an Agency letter dated August 20, 2001.

3. Deletion of the terms "Prescribing Information" from the title of the labeling.

4. Addition of the chemical formula and molecular weight as well as removal of the molecular weight statement to the **DESCRIPTION** section.

5. Addition of the established name in association with the proprietary name throughout labeling to comply with 21 CFR 201.10(g)(1).

6. Addition of a sentence at the end of the **ADVERSE REACTIONS-Leading to Discontinuation of Treatment** section based upon the Agency requested Phase 4 study.

We note that you have incorporated all of our requested revisions, as conveyed in our May 11, 2004 letter, verbatim.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted June 17, 2004/Label Code 061804), which incorporates all of the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
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, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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/

Russell Katz

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