



Food and Drug Administration
Rockville MD 20857

NDA 17-090/S-069

Mallinckrodt Inc.
Attention: Russell D. Reed
Regulatory Affairs
675 McDonnell Boulevard
P.O. Box 5840
Saint Louis, MO 63134-0840

Dear Mr. Reed:

We acknowledge receipt of your supplemental new drug application dated December 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tofranil-PM (imipramine pamoate) 75 mg, 100 mg, 125 mg, and 150 mg Capsules.

Supplemental application S-069, submitted as a "Prior Approval" application, provides for the following revisions to product labeling:

1. The addition of a new subsection under the **PRECAUTIONS** section entitled **Geriatric Use**.
2. The placement of the established name throughout the labeling.
3. The addition of the chemical formula under the **DESCRIPTION** section.
4. Replacement of the **DOSAGE AND ADMINISTRATION** section after the **OVERDOSAGE** section.

Reference is also made to your electronic communication dated March 15, 2004, agreeing to correct the empirical formula in the **DESCRIPTION** section from the current (incorrect) formula of $(C_{19}H_{24}N_2) \bullet C_{23}H_{16}O_6$ to $(C_{19}H_{24}N_2)_2 \bullet C_{23}H_{16}O_6$.

We have completed the review of this supplemental application, S-069, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your draft labeling. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling (text for the package insert) submitted on December 17, 2003. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 17-090/S-069." Approval of this submission by FDA is not required before the labeling is used.

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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