



NDA 12-703/S-093
NDA 12-704/S-046

AstraZeneca Pharmaceuticals
Attention: Judy W. Firor
Regulatory Affairs Director
1800 Concord Pike – P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Firor:

Please refer to your supplemental new drug applications dated December 10, 2001 (NDA 12-703/S-093), and February 6, 2002 (NDA 12-704/S-046), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elavil (amitriptyline hydrochloride) Tablets (NDA 12-703) and Injection (NDA 12-704).

We acknowledge receipt of your submission dated June 19, 2003. Your submission of June 19, 2003, constituted a complete response to our January 22, 2003 action letter.

These "Prior Approval" supplemental new drug applications propose the following revisions to product labeling:

1. The addition of a paragraph in the **ADVERSE REACTIONS-Postmarketing Adverse Events** section regarding cardiomyopathy with the use of Elavil.
2. Additions to the **OVERDOSAGE-Manifestations** section of labeling regarding cardiovascular manifestations of overdose with Elavil.

Additionally, we note that you have incorporated our requested revisions to labeling, as communicated in our January 22, 2003 action letter, verbatim.

We have completed the review of these supplemental applications, 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 19, 2003/Label Code 64201-01), which incorporates the revisions listed. Accordingly, these supplemental applications are 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/

Thomas Laughren
7/29/03 07:47:00 AM
Signed for Russell Katz, M.D.