



NDA 20-622/S-026

Teva Pharmaceuticals, USA
Attention: Tu Dinh Tu, Pharm.D.
Manager, Regulatory Affairs
1510 Delp Drive
Kulpsville, PA 19443

Dear Dr. Tu:

Please refer to your supplemental new drug application dated April 26, 2002, received April 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Copaxone (glatiramer acetate).

This supplemental new drug application provides for the use of an information insert in the pre-filled glass syringe 30-count package. The insert is intended to inform patients who will be using Copaxone pre-filled glass syringe to only use it with the autoject2 *for glass syringe* device and not with the original Copaxone *autoject*, which is for use with a plastic syringe only.

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 (patient package insert submitted April 26, 2002). Accordingly, the 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 Professional" 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 Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

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
8/29/02 09:18:02 AM