DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 16012/S-053

SUPPLEMENT APPROVAL

Teva Women's Health, Inc.
Attention: Ms. Diane Marks
41 Moores Road
PO Box 4011
Frazer, PA 19355

Dear Ms. Marks:

Please refer to your Supplemental New Drug Application (sNDA) dated June 11, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vivactil(protriptyline HCL) 5 and 10mg Tablets.

We also refer to our letter dated May 13, 2014, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for drugs to treat major depressive disorder. This information pertains to the risk of angle-closure glaucoma.

This supplemental new drug application provides for revisions to the labeling for Vivactil consistent with our May 13, 2014 letter.

We have completed our review of this supplemental application. It is approved effective on the date of this letter.

Should you decide to remarket your drug, you will need to submit a "Prior Approval" supplement to incorporate not only these approved changes but also other class labeling revisions for drugs to treat major depressive disorder.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email CDR Renmeet Grewal, Pharm.D., Senior Regulatory Project Manager, at Renmeet.Grewal@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director
Division of Psychiatry 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/

MITCHELL V Mathis
07/17/2014