DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

sANDA 076541/S-019

APPROVAL

Sun Pharmaceutical Industries, Inc.
Attention: Harinath Gangasani
Associate Vice President, Regulatory Affairs
270 Prospect Plains Road
Cranbury, NJ 08512

Dear Sir:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated and received October 15, 2015, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application (ANDA) for Mirtazapine Tablets USP, 7.5 mg, 15 mg, 30 mg and 45 mg.

We acknowledge receipt of your amendment dated October 23, 2015.

The supplemental ANDA, submitted as "Changes Being Effected," and subsequently changed to "Changes Being Effected in 30 Days," provides for:

- Changes in granulation and blending step of the manufacturing process to achieve better tablet hardness.
- Changes in compression parameters to better control the tablet weight.
- Changes in coating parameters for more robust coating process.

We have completed our review of this sANDA, as amended, and it is approved.

We remind you that you must comply with the requirements for the approved ANDA described in 21 CFR 314.80-81.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce

or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files.

Sincerely yours,

Karen A. Bernard -S

Digitally signed by Karen A. Bernard -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000 74783, cn=Karen A. Bernard -S
Date: 2015.11.23 11:40:16 -05'00'

For:

Paul Schwartz, Ph.D.
Director (Acting)
Division of Post Marketing Activities II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Food and Drug Administration
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