DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050475/S-059

APPROVAL LETTER

Valeant Pharmaceuticals North America LLC
U.S. Agent: Valeant Pharmaceuticals International, Inc.
Attention: Peggy McCann, Associate Director, Regulatory Affairs, CMC
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Ms. McCann:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 28, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gris-PEG® (griseofulvin ultramicrosize) Tablets, 125 mg and 250 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes:

- Site transfer of drug product manufacturing, packaging, and release testing from Novartis Consumer Health in Lincoln, Nebraska to Valeant Pharmaceuticals International, Inc. in Laval, Canada (VPII – Laval)
- Addition of (b) (4) as a testing site for incoming drug substance
- Addition of drug substance and compendial testing sites used by (b) (4)
- Minor changes in the manufacturing process, parameters, and equipment
- Addition of drug product specification tests: tests for degradation products (release and shelf life) and package integrity (shelf life)
- updates to the container label and the prescribing information (PI)

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We recommend the following be included in the labeling revisions to be implemented with the next printing:

1. Identify the location of lot numbers and expiration dates on the container label.

Please respond within 14 days upon receipt of this letter with your anticipated timeline for implementing the revisions.

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 Rey Cantave, Regulatory Business Process Manager, at (240) 402-4035.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Division Director (Acting)
Division of Post Marketing Activities I
Office of Lifecycle Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Carton and Container Labeling

Hasmukh Patel

Digitally signed by Hasmukh Patel
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