DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-076/S-042

SUPPLEMENT APPROVAL

Dr. Reddy's Laboratories, Inc
Attention: Srinivasa Rao, Pharm.D.
Senior Director & Head Regulatory Affairs – North America
107 College Road East, 2nd Floor
Princeton, NJ 08540

Dear Dr. Rao:

Please refer to your Supplemental New Drug Application (sNDA) dated January 6, 2016, received January 6, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Habitrol® Patch (nicotine transdermal system) 7 mg, 14 mg, and 21 mg.

This supplemental new drug application provides for the following labeling revisions:

1. Adds four new warning statements to the Drug Facts labeling (DFL) and the Self-help User's Guide (Consumer Information Leaflet) regarding stomach ulcer, diabetes, seizure, and allergic reaction.

2. Revises artwork to incorporate Dr. Reddy's Laboratories branding.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed.

The FPL must be identical to the draft labeling submitted on January 6 and April 5, 2016, for the following stock keeping units and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
7-ct, 7 mg, Outer Carton	January 6, 2016
14-ct, 7 mg, Outer Carton	January 6, 2016
7-ct, 14 mg, Outer Carton	January 6, 2016
14-ct, 14 mg, Outer Carton	January 6, 2016
7-ct, 21 mg, Outer Carton	January 6, 2016
14-ct, 21 mg, Outer Carton	January 6, 2016
28-ct, 21 mg, Outer Carton	January 6, 2016
56-ct Outer Carton kit containing [(28-ct of 21 mg patches, 14-ct of 14 mg patches, and 14-ct of 7 mg patches)]	January 6, 2016
7 mg, Immediate Container (pouch)	April 5, 2016
14 mg, Immediate Container (pouch)	April 5, 2016
21 mg, Immediate Container (pouch)	April 5, 2016
Consumer Information Leaflet (self-help user's guide)	January 6, 2016

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20-076/S-042**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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, call CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton, Container, and Consumer Information Leaflet Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
07/06/2016