DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020076/S-049

SUPPLEMENT APPROVAL

Dr. Reddy's Laboratories, Inc.
Attention: Srinivasa Rao, PharmD (US Agent)
Vice President and 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 and received December 28, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Habitrol (nicotine transdermal system) 7 mg, 14 mg, and 21 mg.

This "Prior Approval" sNDA provides for the following:

- Featuring the proprietary name more prominently on the Principal Display Panel and side panels
- Revision of the Step number graphic on the Principal Display Panel and side panels
- Revised layout and font colors of text on the Principal Display Panel and side panels
- Removal of colored flags around the declaration of net contents and incomplete course of treatment statement on the Principal Display Panel of applicable labels
- Moving the "Habitrol® Take Control™ Support Program" statement to the side panel and removing the associated graphic

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 labeling listed in the table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Representative of Following SKUs	Date Submitted
21 mg, STEP 1		
1-count immediate container (pouch) (21 mg, STEP 1)	N/A	March 2, 2018
2-count carton	N/A	December 28, 2017
7-count carton	N/A	December 28, 2017
14-count carton	N/A	December 28, 2017
28-count carton	N/A	March 2, 2018
14 mg, STEP 2		
1-count immediate container (pouch) (14 mg, STEP 2)	N/A	March 2, 2018
14-ct carton	N/A	December 28, 2017
7 mg, STEP 3		
1-count immediate container (pouch) (7 mg, STEP 3)	N/A	March 2, 2018
14-ct carton	N/A	December 28, 2017
All strengths: 21 mg (STEP 1), 14 mg (STEP 2), or 7 mg (STEP 3) configurations		
56-count (including complete courses of therapy for all 3 STEPs)	N/A	March 2, 2018
Self-help Guide (Consumer Information Leaflet)	N/A	March 2, 2018

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020076/S-049**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that a prior approval supplement must be submitted for additional sized outer cartons. Although no changes were made to the currently approved 1-ct immediate containers (pouch), submit as part of the FPL for this supplement to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement. Additionally, ensure that relevant changes made to the labels and labeling in this sNDA are made to any distributor labeling. The content of the distributor labeling must be identical to the approved applicant holder's label, except for trade name, trade dress, and distributor identification information.

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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

KAREN M MAHONEY
06/27/2018