DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020076/S-043

SUPPLEMENT APPROVAL

Dr. Reddy's Laboratories, Inc.
Attention: Srinivasa Rao, PharmD (US Agent)
Senior Director 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) received January 27, 2016, 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 "Changes Being Effected" sNDA provides for the deletion of the following statement from the ***Warnings*** section of the Drug Facts labeling and consumer information leaflet (self-help user's guide):

When using this product

- do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.

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 22, March 23 and April 11, 2016, respectively, as listed in the following table, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

	Submitted Labeling	Date Submitted
	Outer Carton	
	7-ct, 7 mg, Outer Carton	March 23, 2016
	14-ct, 7 mg, Outer Carton	March 23, 2016
	7-ct, 14 mg, Outer Carton	March 23, 2016
	14-ct, 14 mg, Outer Carton	March 23, 2016
	7-ct, 21 mg, Outer Carton	March 23, 2016
	14-ct, 21 mg, Outer Carton	March 23, 2016
	28-ct, 21 mg, Outer Carton	March 23, 2016
	56-ct kit consisting of [(28-ct of 21 mg patches, 14-ct of 14 mg patches, and 14-ct of 7 mg patches)], Outer Carton	April 11, 2016
	Immediate Container- Pouch	
	7 mg, 1-count	March 23, 2016
	14 mg, 1-count	March 23, 2016
	21 mg, 1-count	March 23, 2016
	Consumer Information Leaflet (self-help user's guide)	January 22, 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 020076/S-043**." 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 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/

THERESA M MICHELE
07/05/2016