



NDA 21-282/S-031

APPROVAL LETTER

Reckitt Benckiser
Attention: Douglas Flint
Manager, Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054

Dear Mr. Flint:

Please refer to your supplemental new drug application dated July 31, 2009, received August 3, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Mucinex® (1200 mg guaifenesin) extended-release bi-layer tablets.

We acknowledge receipt of your submission dated November 11, 2009.

This supplemental new drug application provides for packaging Mucinex® (1200 mg guaifenesin) extended-release bi-layer tablets into 7-count blister packs [REDACTED] (b) (4) material and marketed in a new 14-ct carton package. This supplemental new drug application also provides for the new 7-count blister card and revisions to a 14-count carton label with a repositioned and redesigned clock; revised background colors on the principle display panel; repositioning of the claims statements; formatting changes of the picture of the tablet on the side panel; and under Drug Facts the tamper evident language under “Other Information” was revised to reflect language appropriate for blister packaging and a section entitled “Questions” was added that provides a toll-free telephone number and the statement, “You may also report side effects to this phone number”.

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

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labels (7-count blister card label submitted on July 31, 2009 and 14-count carton label submitted on November 11, 2009), and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The final printed labeling 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 (October 2005)*. 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 21-282/S-031”. Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Michelle Poindexter, Regulatory Project Manager, at (301) 796-4795.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-21282	----- SUPPL-31	----- RECKITT BENCKISER INC	----- MUCINEX

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

/s/

JOEL SCHIFFENBAUER
11/24/2009