DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-891/S-008 **APPROVAL LETTER**

Schering-Plough HealthCare Products
Attention: Charles Lanese
Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Mr. Lanese:

Please refer to your supplemental new drug application dated May 21, 2009, received May 21, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin® (loratadine) Chewable Tablets.

We acknowledge receipt of your submission dated November 2, 2009.

Your submission of November 2, 2009 constituted a complete response to our September 21, 2009 action letter.

This supplemental new drug application provides for the addition of a comparability protocol for changes to the polymeric coating, product contact surface, of the blister lidding material.

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

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 Tu-Van Lambert, Regulatory Project Manager, at (301) 796-4246.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21891	SUPPL-8	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	CHILDREN'S CLARITIN CHEWABLE TAB 5MG

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/s/

HASMUKH B PATEL
03/03/2010