DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-375/S-002

Wyeth Consumer Healthcare
Attention: Barbara Wolfe, Pharm.D.
Associate Director, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Wolfe:

Please refer to your supplemental new drug application dated April 20, 2005, received April 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alavert ® (loratadine) orally disintegrating tablets, 10 mg.

We also refer to your amendments dated July 29 and August 10 and 17, 2005.

This supplemental new drug application provides for two new flavors, bubble gum and citrus burst.

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

The final printed labeling (FPL) must be identical to the submitted labeling (carton, blister cards, shelf trays, and 1-count pouch and dispenser labels submitted April 20, 2005) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-375/S-002." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the word "NEW!" from the bubble gum flavor 12-count carton principal display panel (PDP) after 180 days of marketing. Also, the word "NEW" in the flag "NEW GREAT FLAVOR!" on the carton PDP of the citrus burst flavor 12- and 48- count SKUs and on the 1-count dispenser must be removed after 180 days of marketing.

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, HF-2
FDA
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 Elaine Abraham, Regulatory Project Manager, at (301) 827-2276.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

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

/s/

Charles Ganley

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