DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-555/S-006

Wyeth Consumer Healthcare
Attn: Gabriela Gonzalez, R.Ph.
Manager, Regulatory Labeling and Advertising
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Gonzalez:

Please refer to your supplemental new drug application dated April 23, 2004, received April 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Axid AR (75mg nizatidine) Tablets.

We acknowledge receipt of your submissions dated October 13, 2004, and October 26, 2004.

This supplemental new drug application provides revised labeling incorporating new warning statements to the 30 and 50-count bottle and carton labels and changes to the package insert.

We 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.

The final printed labeling (FPL) must be identical to the submitted labeling (30 and 50-count bottle labels, carton labels and package insert submitted on October 26, 2004), 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 20-555/S-006." Approval of this submission by FDA is not required before the labeling is used.

We also recommend the following labeling change. This change is not a condition of approval. You may incorporate this change in the labeling at the next time of printing and report the revised labeling in the following annual report.

1) Add a horizontal hairline between the "Allergy alert" and "Do not use" subheadings in accordance with 201.66(d)(8).

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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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