DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-520/S-015

Pfizer Consumer Healthcare
Attn: Dawn Parkin
Senior Manager, Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Ms. Parkin:

Please refer to your supplemental new drug application dated August 30, 2004, received August 31, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zantac 75 (75mg ranitidine) Tablets.

We acknowledge receipt of your submissions dated February 16 and February 24, 2005.

This supplemental new drug application provides revised labeling incorporating additional warning language.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (for all package inserts, bottle labels, 1-count pouch, blister carton labels, and bottle carton labels submitted February 24, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-520/S-015**." 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, 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}

Curtis Rosebraugh, M.D., M.P.H.
Deputy 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/

Curtis Rosebraugh

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