CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21698

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-698

Pfizer Consumer Healthcare
Division of Warner-Lambert Company, LLC
Attention: John Jacobs, VP Global Regulatory Affairs
201 Tabor Rd
Morris Plains, NJ 07950

Dear Mr. Jacobs:

Please refer to your new drug application (NDA) dated October 31, 2003, received October 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zantac 150 (ranitidine hydrochloride) tablets.

We acknowledge receipt of your submissions dated November 25, 2003, February 23, March 26, April 14, 28, May 6, 13, June 30, and August 18 and 30, 2004.

This new drug application provides for the use of Zantac 150 (ranitidine hydrochloride) Tablets for:

1. Relieves heartburn associated with acid indigestion and sour stomach, and

2. Prevents heartburn associated with acid indigestion and sour stomach brought on by certain foods and beverages when taken 30 to 60 minutes before eating or drinking.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the revisions listed below.

1. The content of the blister carton, bottle carton, and the 1-count pouch labeling should be identical.

2. In the package insert, under the "Do not use" subheading, in the first bullet that begins, "if you have trouble or pain . . ." replace the misspelled word "bloddy" with the word "bloody" and add periods as shown, so that the bullet reads " if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor."

The final printed labeling (FPL) must be identical to, except for including the revisions listed, the enclosed labeling (package insert and bottle carton labeling submitted on August 30, 2004, and 1 tablet pouch labeling, blister backing immediate container and bottle immediate container labels submitted on May 6, 2004), and all carton labeling, must be in the "Drug Facts" format (21 CFR 201.66). These revisions are terms of the NDA approval. Marketing the product(s) before making the revisions,

exactly as stated, in the products' labeling and in the required format may render the product misbranded and an unapproved new drug.

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 NDA 21-698.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirements for this application.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one of the copies to the Division of Gastrointestinal and Coagulation Drug Products and the other copy, along with the labeling, to Division of Over-the-Counter Drug Products, HFD-560.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, call Keith Olin, Regulatory Project Manager, R.Ph. at (301) 301-827-2293.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Charles J. Ganley
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

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
8/31/04 04:54:37 PM

Joyce Korvick
8/31/04 05:08:35 PM