



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-520/S-010

Warner Lambert
Attention: P. Georgio Fontana, Ph.D.
Senior Director, Global Regulatory Affairs
170 Tabor Road
Morris Plains, NJ 07950

Dear Dr. Fontana:

Please refer to your new supplemental drug application (SNDA) dated March 12, 2001, received March 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zantac ® 75mg Tablets.

This supplemental new drug application provides for the labeling in Drug Facts format for the 4,10, 20, 30, 60, 70, 80, 110 count packages. We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the application is approved effective on the date of this letter.

The following revisions should be made within 180 days or at the time of the next printing.

I. Principal Display Panel (PDP)

1. The word "**New**" in the statement "**New 110 COUNT BOTTLE**" on the 110-count bottle carton needs to be removed after 6 months of marketing.

II. Drug Facts Labeling

1. Under the "**Active ingredient**" heading, revise "Ranitidine hydrochloride 84 mg; equivalent to 75 mg ranitidine" to read "Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)".
2. Under the subheading "**Allergy alert:**" revise to read: "Do not use if you are allergic to ranitidine or other acid reducers".
3. In the **Warnings** section, under the subheading "**Do not use**" revise to read:
Do not use
 - if you have trouble swallowing
 - with other acid reducers

4. Delete the subheading section and statements under "**When using this product**".
5. Under the subheading "**Stop use and ask a doctor if**" revise to read:
Stop use and ask a doctor if
 - stomach pain continues
 - you need to take this product for more than 14 days
6. Under the *Directions* section, revise the directions as follows:
 - adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water
 - to **prevent** symptoms, swallow 1 tablet with a glass of **water 30 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - can be used up to twice daily (up to 2 tablets in 24 hours)
 - children under 12 years: ask a doctor
7. Under the *Other information* section, revise as follows:
 - a. In the first bulleted statement, revise to read:
 - do not use if the carton or individual blister unit is open or torn
 - b. Revise the bulleted statement "Zantac 75 tablets are sodium and sugar free", to read:
 - this product is sodium and sugar free
8. Under the *Inactive ingredients* section delete the word "and" before the word "triacetin".

In addition, the following labeling requirements can be submitted in the next annual report. These requirements should reflect the minor revisions as specified in this approval letter.

1. Submission of the blister pack unit labeling for the 4, 10, 20, and 30-count package sizes.
2. Submission of the immediate bottle label for the 60, 70, 80, and 110-count bottles.
3. Submission of the consumer information leaflets for all package sizes.
4. For consistency with other marketed OTC acid reducer drug products, the "**Tips for managing heartburn**" statements should be included either right after the Drug Facts labeling or in the consumer information leaflet (package insert).

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (immediate container and carton labels submitted March 12, 2001) and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the NDA approval. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-520." Approval of this submission by FDA is not required before the labeling is used.

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

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 Daniel P. Keravich, M.S., M.B.A., Regulatory Health Project Manager, at 301-827-2248

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Director
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