

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**75-311**

**ADMINISTRATIVE DOCUMENTS**



**REVIEW OF PROFESSIONAL LABELING  
DIVISION OF LABELING AND PROGRAM SUPPORT  
LABELING REVIEW BRANCH**

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ANDA Number: 75-311      Date of Submission: December 29, 1997

Applicant's Name: Teva Pharmaceuticals USA

Established Name: Famotidine Tablets USP, 20 mg & 40 mg

Labeling Deficiencies:

1. GENERAL COMMENTS

Replace the "Caution: Federal law..." statement with "Rx only" or "R only" on labels and labeling. We refer you to the Guidance for Industry, "Implementation of Section 126, Elimination of Certain Labeling Requirements, of the Food and Drug Administration Modernization Act of 1997", at the internet site: <http://www.fda.gov/cder/guidance/index.htm> for guidance.

2. CONTAINER - 30's, 100's, 180's, & 1000's

a. Your statements regarding Container/Closure Systems indicate that a Non-CRC (Metal screw cap) will be used for the package size of 100's. However, the Poison Prevention Packaging Act notes that special packaging (child-resistant closures) should be the responsibility of the manufacturer when the container is clearly intended to be utilized in dispensing (unit-of-use packaging). Please note that the innovator declares the bottles of 100's as unit-of-use packaging. We believe that your package size of 100's must comply with the Act. Please comment.

b. We encourage you to differentiate the two different strengths from each other, by using contrasting colors and/or boxing, or any other means.

c. Revise the storage requirement to read "Store at controlled room temperature 15°..." as found in your insert labeling.

- d. 1000's - Include the following statement:

This is a bulk package and not intended for dispensing.

3. INSERT

a. GENERAL

It is preferable to use the term "to" rather than a hyphen when expressing a range.

b. DESCRIPTION

i. First sentence:

The active ingredient in famotidine tablets is... [add "tablets"]

- ii. We encourage you to revise the chemical name to be same as the second name appearing in the official monograph for famotidine in USP 23.

- iii. The molecular formula... [rather than "empirical"]

- iv. Revise the molecular weight to read "337.45" to be in accordance with USP 23.

v. Third paragraph:

- A) First sentence - Revise to read as follows:

Each tablet, for oral administration contains 20 mg or 40 mg of famotidine. In addition, each tablet contains the following inactive ingredients:...

- B) Please note that there are two USP/NF monographs for lactose. Please revise accordingly . [i.e. anhydrous lactose or lactose monohydrate]

- C) Identify the botanical source of starch. [e.g., corn starch]

c. INDICATIONS AND USAGE

Famotidine tablets are indicated... [add "tablets"]

d. PRECAUTIONS (Pediatric Use):

... in pediatric patients have... [rather than "children"]

e. HOW SUPPLIED

i. Revise to read as follows:

Each famotidine tablet, USP contains xx mg of famotidine and are available... [two places]

ii. Describe your products as "unscored".

iii. We encourage the inclusion of the "Dispense in..." statement as found on your container labels.

Please revise your labels and labeling, as instructed above, and submit 4 draft copies for a tentative approval or 12 final printed copies for a full approval of this application. If draft labeling is provided, please be advised that you will be required to submit 12 final printed copies of all labels and labeling at least 60 days prior to full approval of this application. In addition, you should be aware that color and other features (print size, prominence, etc) in final printed labeling could be found unacceptable and that further changes might be requested prior to approval.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with the last submitted labeling with all differences annotated and explained.

*Jerry Phillips for*

Jerry Phillips

Director

Division of Labeling and Program Support

Office of Generic Drugs

Center for Drug Evaluation and Research