

February 24 3:21:00 '00 FEB 29 19:24

Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 98N-0337
NDA 20-902: PEPCID AC GELCAPS
(Famotidine 10 mg)

Conversion of Request for Exemption to Request for Deferral from Drug Facts Rule

Dear Sir or Madam:

Please refer to NDA 20-902 for Pepcid AC Gelcaps approved on August 5, 1999 and to our submission of July 2, 1999 which indicated that the sample pouch package was being deleted from the new drug. Also refer to our Application for Exemption (submitted 10/22/99) which requested relief from some of the requirements of the Drug Facts format for sample pouch configuration.

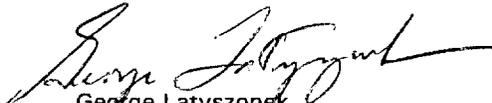
As a result of feedback provided by The Agency and based on The Agency's response (02/04/2000) to CHPA's Citizen Petition, we are requesting our application for exemption be converted to a request for deferral from the Drug Facts format requirements for a period of nine months. The nine-month period will enable us to acquire, implement and validate the equipment necessary to produce compliant sample pouches.

As you are aware, activities such as package design and stability evaluations are initiated early in a product's development process. The sample pouches intended for distribution were designed and tested long before the May 16, 1999 effective date of the OTC labeling rule. Therefore, it is unrealistic to expect compliance for a product whose NDA approval was granted only two months after the rule's effective date.

Attached is the proposed sample pouch, which will be distributed during the deferral period. It is identical to that included in our exemption request and reflects all of the text currently approved for use in Pepcid AC Gelcap labeling, with the exception that inactive ingredients are not listed.

If there are any questions, please call me at (215) 273-7152 or in my absence Edwin Hemwall, PhD, at (610) 397-2306.

Sincerely,


George Latyszczek
Director Regulatory Affairs

mhg
Attachment

cc: Charles Ganley, MD/HFD-560

98N-0337

APP 8

While folded on line,
tear open at slit



Pepcid AC
Famotidine Tablets 10mg/®
Acid Reducer

Do not use if pouch is open or torn.



1 Gelcap
(Gelatin Coated,
Capsule Shaped Tablet)

Drug Facts
Active ingredient (in each gelcap)
Famotidine 10 mg.....**Purpose**
Acid reducer

Uses • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings
Allergy alert: do not use if you are allergic to famotidine or other acid reducers
Do not use • if you have trouble swallowing • with other acid reducers

While folded on line,
tear open at slit

Drug Facts (continued) X [000000]

Stop use and ask a doctor if • stomach pain continues • you need to take this product for more than 14 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • adults and children 12 years and over:
• to relieve symptoms, swallow 1 gelcap with a glass of water
• to prevent symptoms, swallow 1 gelcap with a glass of water at any time from 15 to 60 minutes before eating food or drinking beverages that cause heartburn • do not use more than 2 gelcaps in 24 hours • children under 12 years: ask a doctor

Other information • read the directions and warnings before use • store between 25-30C (77-86F) • protect from moisture

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LOT XXXXX
EXP XXXX

Actual size

While folded on line,
tear open at slit



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Famotidine Tablets 10mg/®
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EXP XXXX

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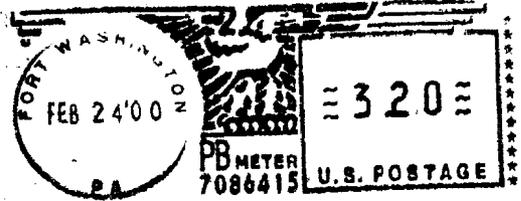
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