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October 22, 1999

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)

APPLICATION FOR EXEMPTION

Dear Sir or Madam:

Please refer to NDA 20-902 for Pepcid AC Gelcaps approved on August 5, 1999. Also refer to our submission of July 2, 1999 which indicated that the sample pouch package was being deleted from the New Drug Application but that it would be resubmitted with an accompanying request for an exemption from the OTC labeling standardized format requirements.

At this time we are submitting this application for exemption for a sample pouch whose contents will consist of one Pepcid AC Gelcap. This application consists of justification for granting the exemption, draft labeling, annotated and current labeling.

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 Latyszonek
Director Regulatory Affairs

mhg

cc: Charles Ganley, MD
Lilia Talarico, MD

98N-0337

APP 7

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CURRENT LABELING



Drug Facts (continued)
Questions or comments?
1-800-755-4008

Pepcid

AC

Famotidine Tablets 10mg/Acid Reducer®

Gelcaps

Relieves & Prevents Heartburn Due To Acid Indigestion

6 Gelcaps (Gelatin Coated,
Capsule Shaped Tablets)

Just One Per Dose

Distributed by
Schering-Plough • MERCK
CONSUMER PHARMACEUTICALS CO.
PORT WASHINGTON, PA 19384 USA
A registered trademark of Merck & Co., Inc.

Questions or Comments
Please Call 1-800-755-4008

Pepcid
AC
Gelcaps

Do not use if the individual blister unit is open or torn.
PEPCID AC is Now Available in an Easy-to-Swallow Gelcap
• 1 gelcap relieves heartburn due to acid indigestion (Read Package Insert before use).
• PEPCID AC prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

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

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

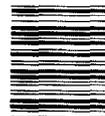
- adults and children 12 years and over:
 - to relieve symptoms, swallow 1 gelcap with a glass of water
 - to prevent symptoms, swallow 1 gelcap with a glass of water at any time from 15 to 60 minutes before eating food or drinking beverages that cause heartburn
 - do not use more than 2 gelcaps in 24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

Drug Facts (continued)

Other information • read the directions and warnings before use • protect from moisture
• keep the carton and package insert. They contain important information. • store at 25° - 30°C (77° - 86°F)

Inactive ingredients benzyl alcohol, black iron oxide, butylparaben, castor oil, edetate calcium disodium, FD&C red #40, gelatin, hydroxypropyl methylcellulose, magnesium stearate, methylparaben, microcrystalline cellulose, pre-gelatinized corn starch, propylene glycol, propylparaben, sodium lauryl sulfate, sodium propionate, talc, titanium dioxide

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REQUESTED
EXEMPTIONS

We are requesting that the pouch package be exempt from certain provisions of 21 CFR Part 201. Due to the small size of the package it is virtually impossible to accommodate the format and some of the content requirements set forth in the 21 CFR 201.66 format and content requirements for over-the-counter (OTC) drug product labeling. These pouches are intended solely as sample vehicles which are not sold at the retail level. Such pouches are commonly used by the industry to establish product awareness among consumers and to provide an opportunity to evaluate a new product without expenditure of money. Millions of pouches are distributed annually and we are unaware of any evidence which would indicate that their distribution has posed any threat to public safety. We have made sure that the textual content is exactly as it was approved in the NDA for Pepcid AC Gelcaps. None of the labeling content falls below the agency's mandated 6pt. minimum size. Certain adjustments have been made to the size of the headings. However through the use of bolding and color contrast legibility has not been compromised. We believe that we have achieved our goal of minimal deviation from the requirements set forth in the final rule.

201.66(c)(8) Inactive ingredients

After including all of the required headings, subheadings and NDA required and approved text which is critical to the safe and effective use of the product, no space is available for listing the inactive ingredients. We are requesting an exemption from this requirement.

201.66(d)(10)(ii) Modifications for Small Packages

We are requesting an allowance to reduce the size of the title "Drug Facts (Continued)" from 7 pt. to 6.5 pt. and to reduce the size of the headings from 7 pt. to 6 pt.

201.66(d)(8) and 201.66 (d)(10)(v) Hairlines and Barlines

We are requesting exemption from the requirement which mandates the use of hairlines and barlines. The use of bolding and color contrast sufficiently separates the headings and subheadings.

**PROPOSED
LABELING**

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 [0000000]

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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FORT WASHINGTON, PA 19034 USA © Registered trademark of Merck & Co., Inc.

LOT XXXXXX
EXP XXXXX

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LOT XXXXXX
EXP XXXXX

(OTC) GELCAP POUCH-CR

<i>Drug Facts</i>	7.5 pt. Univers 65 Bold Oblique (94% horiz. scale)
<i>Uses (subheads)</i>	6 pt. Univers 67 Condensed Bold Oblique (94% horiz. scale)
relieves (text)	6 pt. Univers 57 Condensed (90% horiz. scale)
• (bullets)	5 pt. Univers 57 Condensed (90% horiz. scale)
Do not (text)	6 pt. Univers 67 Condensed Bold (85% horiz. scale)
<i>Drug Facts</i> (cd)	6.5 pt. Univers 65 Bold Oblique (85% horiz. scale)
(continued)	6.5 pt. Univers 55 (85% horiz. scale)

(OTC) GELCAP POUCH-CR

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Headings

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Hairlines and Barlines

Not Used

Drug Facts (Continued)

Reduced from 7 pt. to 6.5 pt.

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Drug Facts (continued) X [0000000]

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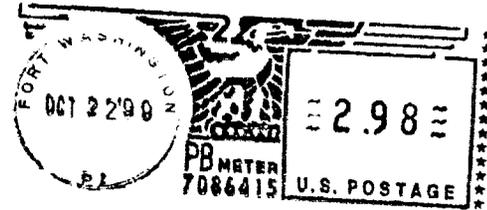
Inactive Ingredients

Not Listed

Mr. George Latyszzonek/096
JOHNSON & JOHNSON o MERCK
Consumer Pharmaceutical Co.
7050 Camp Hill Road
Fort Washington, PA 19034

Z 376 815 088

MAIL



Request for Exemption from 21 CFR 201.66

(OTC Labeling Format)

Docket No. 98N-0337

Johnson & Johnson o **MERCK**

CONSUMER PHARMACEUTICALS CO.
CAMP HILL ROAD, FORT WASHINGTON, PA 19034 (215) 233-7661

TO

RETURN REQUESTED

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

FRAGILE • FRAGILE • FRAGILE