

## Document Information Page

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**Application #(s):** NDA 20958/S-002

**Document Type:** Supplement Letter  
**Document Group:** Approval Letters  
**Document Name:** Approval letter based on enclosed/submitted labeling text  
**Letter Code:** SNDA-II

**COMIS Decision:** AP: APPROVAL

**Drafted by:** dpk/October 29, 2001  
**Revised by:** MJW 11/06/01  
**Initiated by:** MJW 11/06/01  
**Finalized:** LMK 11/06/01  
**Filename:**

**DFS Key Words:**

**Notes:**

**Linking Instructions:** If this is the first action on the application, link the outgoing letter to the initial submission, RS, AR, or FO coded incoming document for the supplement being acted on, as appropriate. Otherwise, the outgoing letter must be linked to the major amendment submitted in response to the previous action letter.  
In addition, the outgoing document should also be linked to all associated amendments and correspondences included in the action.

**END OF DOCUMENT INFORMATION PAGE**

The letter begins on the next page.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 20958/S-002

Merck Research Laboratories  
Attention: Brenda A. McGuire, B.S., R.N.  
Regulatory Affairs  
P.O. Box 4, BLA-33  
West Point, PA 19486

Dear Mrs. McGuire:

Please refer to your supplemental new drug application dated July 5, 2001, received July 6, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid® Complete [famotidine 10 mg/antacid (calcium carbonate 800 mg, and aluminum hydroxide 165 mg)] Chewable Tablets.

We acknowledge receipt of your submissions dated July 11, August 03 and October 04, 08, 11, 15, 24 and 29, 2001.

This supplemental new drug application provides for a berry-flavored chewable tablet.

We have completed the review of this supplemental 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 supplemental application is approved effective on the date of this letter.

As agreed upon in your submission dated October 30, 2001, the requirements are as follows:

1. In the ***Other information*** section of the bottle labeling for all container sizes, the bulleted statements need to be vertically aligned.
2. The graphics associated with the Statement of Identity (i.e., "Acid Reducer + Antacid") on the principal display panel will be modified in order to enhance its prominence in conjunction with the proprietary name.
3. The word "***NEW***" will be deleted from packaging after 180 days of marketing.

The final printed labeling (FPL) must be identical to the attached labeling (immediate container, trade and sample pouch labels, carton labels and package insert) submitted on July 5, 2001, and include the minor editorial revisions indicated above. The final printed labeling must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

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 supplement NDA 20958/S-002." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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  
Division of Over-the-Counter Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

7/5/2001

20-958

SCF-002

DATE NO.	FC-C-752
DESIGNER	JOHNSON & MERCK
ARTS	PRINTED
SIZE	10
DATE	10/29/98
CARTON, SEAL END	THERMAL
APPROVED	3-1/4 X 1-1/8 X 3-3/4

## NOTES:

- 1) DRAWING SHOWN PRINT SIDE UP
- 2) ALL DIMENSIONS IN INCHES
- 3) TOLERANCES UNLESS SPECIFIED:  
FRACTIONS  $\pm 1/32$ , ANGLES  $\pm 1^\circ$
- 4) BASED ON PCI DVG. NO. L30126 (10-8-98)
- 5) ALL LIVE COPY & TEXT TO BE A MINIMUM OF  $1/16"$  FROM ALL SCORES & CUTS.
- 6) LOT & EXP. DATE AREA
- 5) VISIONS BARCODE AREA
- 6) NO VARNISH AREA
- 7) ---- NO PRINT

Labeling Format Information:

Fonts: Univers condensed, bold and bold italic.  
 Drug Facts: 9 pt | Leading: 6.5 pt  
 Header: 8 pt | Bullets: 5 pt  
 Subheader: 6 pt | Barlines: 2.5 pt  
 Body Text: 6 pt | Hairlines: .5 pt  
 Drug Facts (continued): 8 pt

Horizontal Scale: 94%

Average Kerning: -4

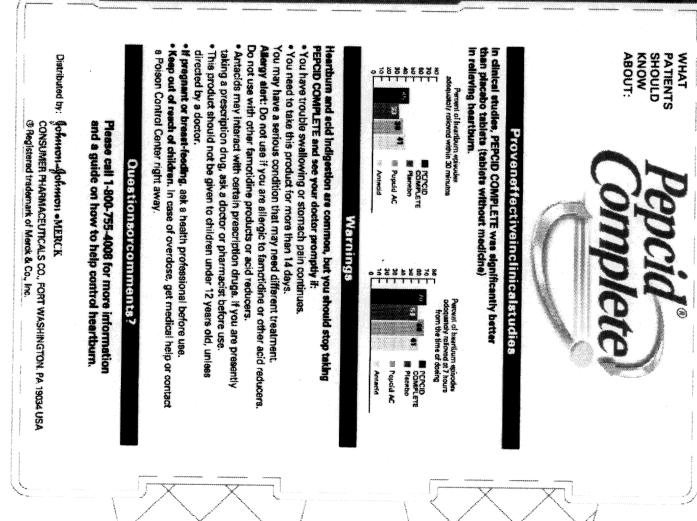
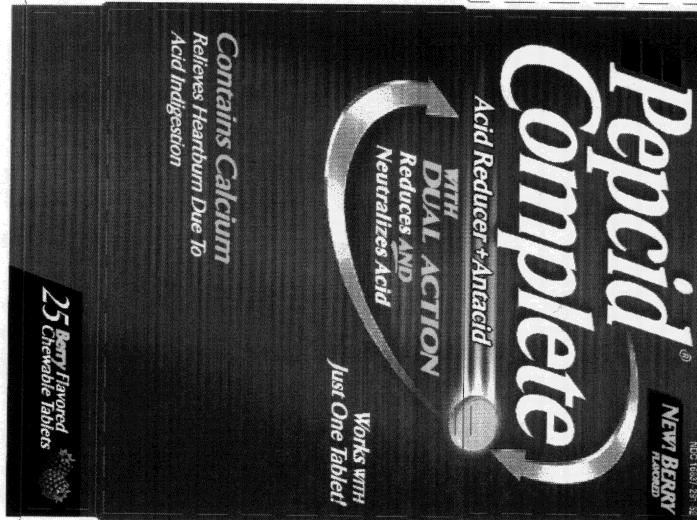
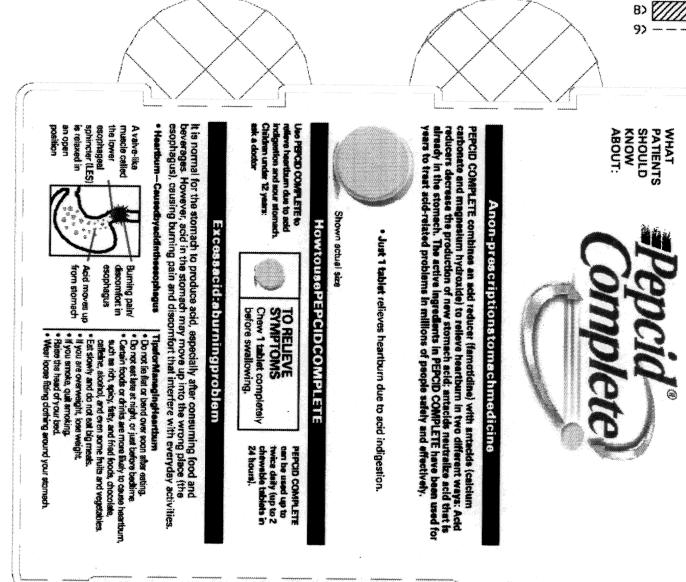
JOB DESCRIPTION <u>CTN PEPCID COMP BERRY CHEW TAB 5</u>		DESIGN FIRM MUST FILL IN THIS BLOCK		THIS BLOCK FOR McNEIL GRAPHICS USE ONLY!		THIS BLOCK IS FOR McNEIL CHC PURPOSES ONLY!	
FILE #	3003222	VERSION	A-1	PRINTER		INITIALS	DATE
DATE	May 31, 2001	DIE VINYL	FC-C-752.00	GRAPHIC ANALYST		REGULATORY	
PS IMAGE #	M296/M298/ M299/M245/LIVE ART	KEY CONTACT	Tony Nucera	UPC #		MEDICAL	
 <u>Great Atlantic Graphics Inc.</u> 200 Great Valley Parkway Malvern, PA 19355 (610) 296-8711 Fax:(610) 640-4739		COMPARED BY:		PART NUMBER			
		DESIGN PROGRAM	ILLUS. ver. 8.0	PCNNPA NUMBER			
		MAXIMUM OF FIVE COLORS PER COMPONENT		FCC#			
		YELLOW	CYAN	PACKAGING LOCATION			
		BLACK	DK BLUE	COLOR STANDARD			
		RED		VALIDITY DATE			
THIS DESIGN BLOCK MUST BE SAVED WITH FILE AND PRINTED ON THERMAL.							

**NOTE**

- 1) DRAWING SHOWN PRINT SIDE UP  
 2) ALL DIMENSIONS IN INCHES  
 3) TOLERANCES UNLESS SPECIFIED:  
 FRACTIONS  $\pm \frac{1}{32}$ , ANGLES  $\pm 1^\circ$   
 4) BASED ON PCI DWG. NO. L32401R3 (5-11-00)  
 5) ALL LIVE COPY & TEXT TO BE A MINIMUM OF  
 $\frac{1}{16}$ " FROM ALL SCORES & CUTS.  
 6) NO PRINT AREA  
 7) NO VARNISH/NO PRINT AREA  
 8) NO PRINT AREA: RESERVED FOR LOT & EXP DATE ONLINE PRINTING  
 9) --- NO PRINT

ARL/DK	3	8/16/00	REVISED LD
ARL/DK	E	8/16/00	ADDED LD
ARL/EM	I	8/16/00	UPDATED TD
INIT.	ND:	DATE	

ARS/CH	3	8/16/00	REVISED LOT & EXP AREA	DR
ARS/CH	2	8/15/00	REVISED LOT & EXP AREA	P
ARS/BN	1	5/16/00	UPDATED TO PCI DWG REV 3	DR
INIT.	NO.	DATE	REVISIONS	APL



5-11-00  
MINIMUM OF

REV. NO.	FC-D-706	McNeil
DRAWN	ARS	Deseret Refinery Camp Hill Road, Port Washington, PA 18930
PILOT	11	TITLE:
SCALE		DISPENSIT
AR5/CH 3	8/16/00 REVISED LOT & EXP AREA	DATE 4/21/00
AR5/CH 2	8/16/00 ADDED LOT & EXP AREA	
AR5/CH 1	8/16/00 UPDATED TO PCI DVG REV 3	
INIT. NO.	DATE	REVISIONS
		APPROVED

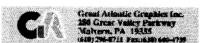
DR. LOT & EXP DATE ONLINE PRINTING

#### Labeling Format Information:

Font: Univers condensed, bold and bold italic.  
**Drug Facts:** 10 pt **Leading:** 8 pt  
**Header:** 9 pt **Bullets:** 5 pt  
**Subheader:** 6.5 pt **Barlines:** 2.5 pt  
**Body Text:** 6.5 pt **Hairlines:** .5 pt  
**Drug Facts (continued):** NA

Horizontal Scale: 94% Average Kerning: -4

JOB DESCRIPTION DISP PEPCID COMP\_E  
FILE # 3003222  
DATE May 31, 2001  
M295, M298, M299  
PS IMAGE # M300, M245, LIVE ART

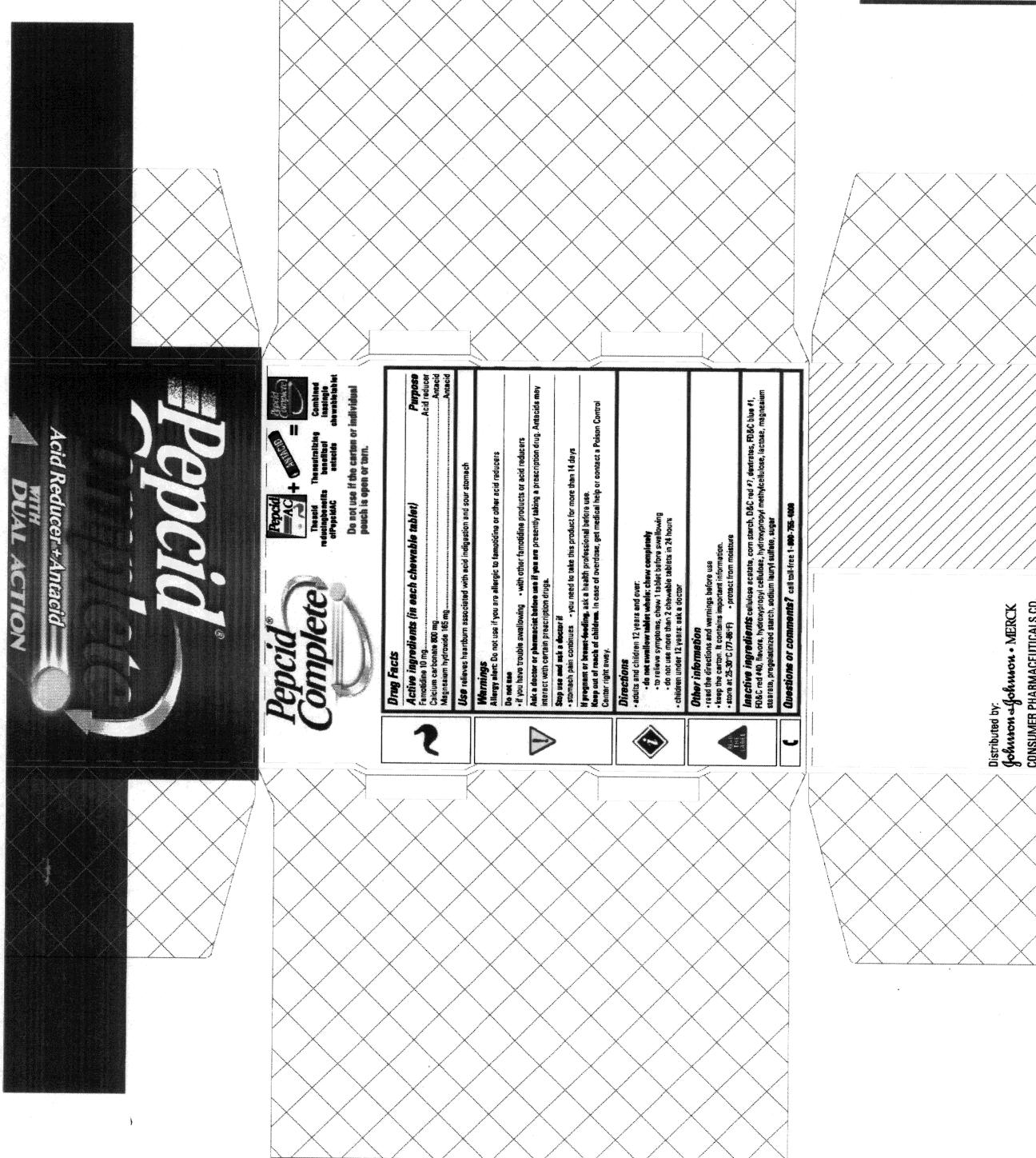


Great Atlantic Cosmetics Inc.  
100 Great Valley Parkway  
Exton, PA 19341-2712 • FAX: 610-661-7125

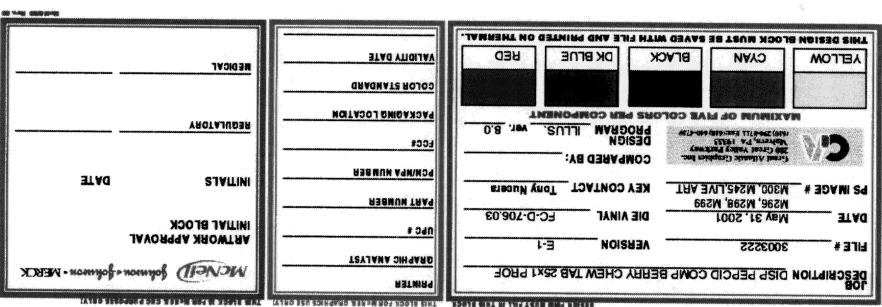
MAXIMUM OF FIVE COL

YELLOW CYAN BLA

THIS DESIGN BLOCK MUST BE SAVED W



Distributed by  
**Johnson & Johnson • MERCK**  
CONSUMER PHARMACEUTICALS CO.



Specifying Formal Information:		Average Length: 4	Total Central Scale: 94%
Paragraph Features:	10 pt	Drawing Features (continued):	NA
Text Features:	8 pt	Body Text:	6.5 pt
Labels:	8 pt	Subtitles:	6.5 pt
Buttons:	10 pt	Bullets:	5 pt
Icons:	10 pt	Harpoons:	5 pt
Unires Components:	bold, italic,		

Digitized by srujanika@gmail.com

Avg Horizontal Scale: 94%

| Drug Facts (continued): NA

**Body Text:**

**Header:**

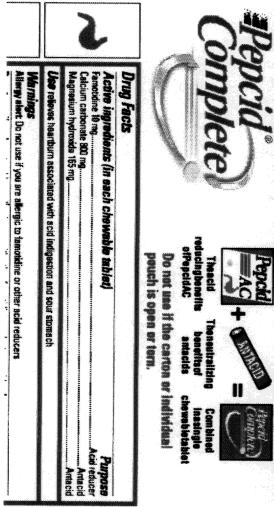
Drug Facts

**Fonts:** Univers Condensed, bold

**Labeling Format Information:**



		<p><b>Instructions for use:</b></p> <ul style="list-style-type: none"> <li>- keep out of reach of children.</li> <li>- if pregnant or breast-feeding: ask a health professional before use.</li> <li>- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</li> </ul>
		<p><b>Other information:</b></p> <ul style="list-style-type: none"> <li>- read the directions and warnings before use</li> <li>- keep out of reach of children; maximum recommended dose.</li> <li>- protect from sunlight.</li> <li>- store at 15-25°C (59-77°F)</li> </ul>
<p><b>Indicative ingredients:</b> cellulose, corn starch, D&amp;C blue #1, FD&amp;C red #6, flavors, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, pregelatinized starch, sodium lauryl sulfate, sugar</p>		<p><b>Dosage and administration:</b> eat tablets 1-2 per day.</p>
<p><b>Contraindications:</b></p>		<p><b>Storage:</b> store in a dry place, protected from light.</p>



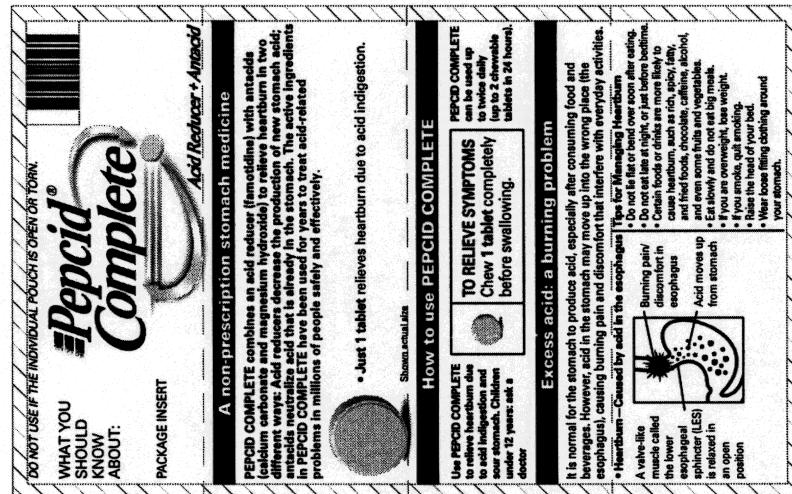
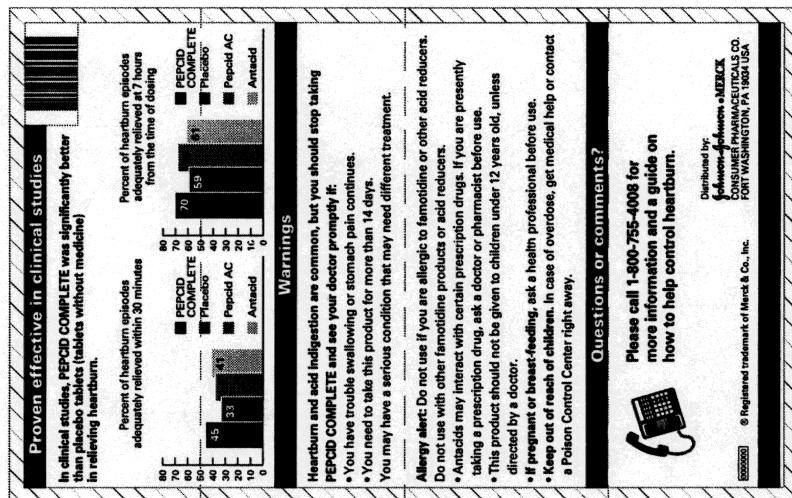
Liberating Formal Information:		Horizontal Scale: 90%	
Drugs:	10 drs.	Body Text:	6 pt.
Drugs:	10 units condensed, bold and bold	Header:	8.5 pt.
Fonts:	Times New Roman	Subheader:	6.5 pt.
Leaders:	8.5 pt.	Braille:	6 pt.
Braille:	10 drs.	Horizontal Scale (continued):	N/A

FILE #	300222	DESCRIPTION	CNT PEPCID COMP BERRY CHEW TAB 35
PRINTER	GRAPHIC ANALYST	VERSION	C-1
DATE	May 31, 2001	DE# VINYL	FC-D-707.03
ARTWORK BLOCK	M292/M296/M298	ARTWORK NUMBER	M292/LIVE ART
METAL BLOCK		PART NUMBER	Tony Nucera
DATE	05/29/2001	KEY CONTACT	DK BLUE
INTLALS		COMPARED BY:	DESIGN ILLUS ver. 8.0
DATE		REGULATOR	PKG LOCN
COMPARED BY		COLON STANDARD	COLON STANDARD
DK BLUE		ADVERT DATE	ADVERT DATE
BLACK		REDCAL	REDCAL
VELLOW		DK BLUE	DK BLUE
CMYK		BLACK	BLACK
MANUFACTURE OF THIS COLOR MARK IS SUBJECT TO SEVERAL PATENTS AND TRADEMARKS			



The logo consists of the letters 'ACI' in a bold, italicized font, with a horizontal line above it containing the letters 'ACI'. Below the letters is a small square containing the number '10'. To the right of the logo is a rectangular stamp with the word 'PARKING' at the top and 'CASHIERED' at the bottom.

Horizontal Scale: 94%	Average Length:
During Events (continued):	NA
Body Text:	NA pt
Headlines:	8 pt
Subheads:	8 pt
Bulletins:	10 pt
Lead-in:	10 pt
Font:	Univers condensed, bold and bold italic.



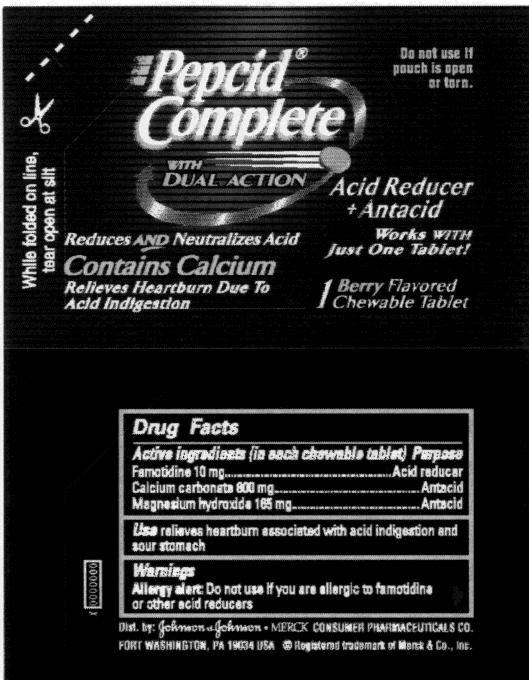
BROCHURE - 4C		BROCHURE - 4C	
DESIGNER: MELISSA O' MIERICK		DESIGNER: MELISSA O' MIERICK	
PRINTED: 10/10/97		PRINTED: 10/10/97	
REVIEWED BY: BARS		REVIEWED BY: BARS	
INIT.	NR.	DATE	REVISIONS
MWS	1	11/24/97	APPENDIX
6.63 L X 4.19 W			



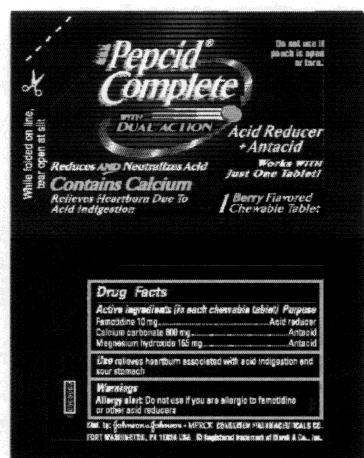
## NOTES:

- 1) ALL DIMENSIONS IN INCHES.
- 2) PRINT REPEAT TOLERANCE NOT TO EXCEED  $\pm 1/32$  OVER 12 IMPRESSIONS (35.508  $\pm .031$ )
- 3)  NO COPY AREA
- 4)  LOT & EXP. DATE AREA

DIV. NO.	UNWIND-131	McNEIL
PRINT	ARS	CONSUMER PRODUCTS CO.
PLATE	NTS	CAMP HILL ROAD, FORT WASHINGTON, PA 19034
DATE	3/31/00	TITLE
INIT.	REV.	CR POUCH MATERIAL UNWIND 2.959 L X 3.828 W



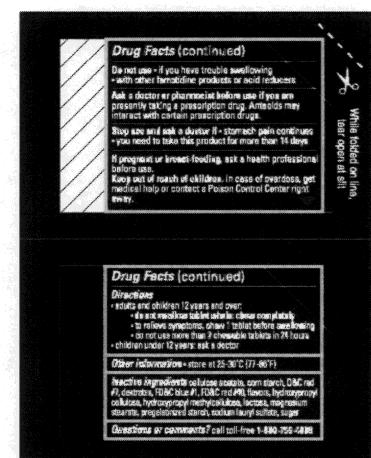
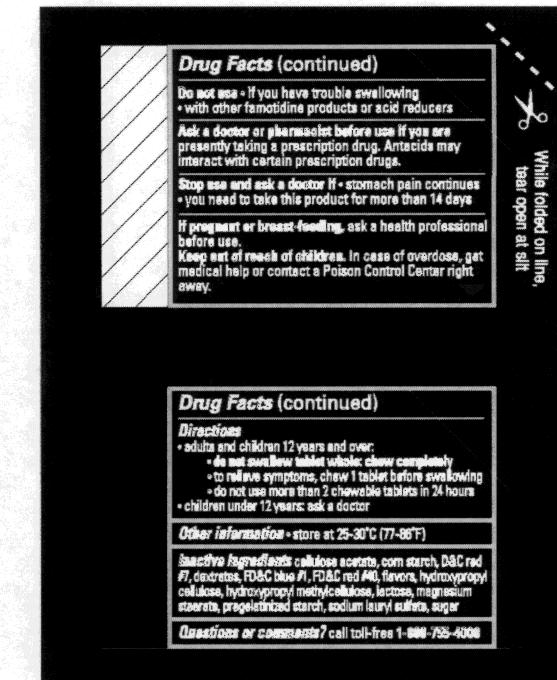
150%OFSIZE



<b>Labeling Format Information:</b>	
Fonts:	Univers condensed, bold and bold italic.
Drug Facts:	8 pt
Header:	Leading: 6 pt
Subheader:	7 pt
Body Text:	6 pt
Drug Facts (continued):	8 pt
Horizontal Scale:	84-94%
Average Kerning:	4

DRUG FACTS MUST FILL IN THIS BLOCK

JOB DESCRIPTION	POUCHPEPCIDCOMPBERRYCHEWTABPROF		
FILE #	3003293	VERSION	
DATE	May31,2001	UNWIND-131	BY VINYL
PS IMAGE #	LIVEART	KEY CONTACT	Tony Nucera
COMPARED BY: _____			
DESIGN PROGRAM ILLUSB.0 ver. _____			
MAXIMUM OF FIVE COLORS PER COMPONENT			
 Great Atlantic Graphics Inc. 280 Great Valley Parkway Exton, PA 19341-2729 (800) 286-8711, Fax (800) 668-1729			
THIS DESIGN BLOCK MUST BE SAVED WITH FILE AND PRINTED ON THERMAL			



THIS BLOCK FOR McNEIL GRAPHICS USE ONLY

THIS BLOCK IS FOR McNEIL GBC PURPOSES ONLY

PRINTER	McNeil
GRAPHIC ANALYST	Johnson & Johnson • MERCK
UPC #	
PART NUMBER	
PCNNPA NUMBER	
FCC#	
PACKAGING LOCATION	
COLOR STANDARD	
VALIDITY DATE	
REGULATORY	
MEDICAL	

NOTES:  
 1) ALL DIMENSIONS IN INCHES  
 2) UNLESS OTHERWISE SPECIFIED  
 3) DRAWING SHOWN PRINT SIDE UP  
 4)  PRINT NEED  
 5)  PART NUMBER AREA MUST USE  
 6)  NO BOX AROUND PART NUMBER  
 7)  NO PRINT, NO COLOR & NO VARNISH AREA  
 8)  LOT# AND EXP# PRINT AREA

DRW#	3	REV#	MOVES PART NO AHEAD OF LINE LINES	DWG. NO.	LB-PS-848
AR5/AR6	2	U/W#	ADDED TOLERANCES	DRAWN	ARS
AR5/C/P	1	2/26/99	CHG'D LOWER LEFT CORNER	PLT.#	11
INT'L.	NO.	DATE	REVISIONS	DATE	2/26/99
				APPROVED	

Johnson & Johnson • MERCK  
 CONSUMER PHARMACEUTICALS CO.  
 CAMP HILL ROAD, FORT WASHINGTON, PA 19034

TITLE: BOOKLET LABEL FOR FACT 200CC BOTTLE

**RESERVED FOR COUPON TEXT**



**Pepcid® Complete**  
Acid Reducer + Antacid  
WITH DUAL ACTION  
Reduces AND Neutralizes Acid  
Contains Calcium Relieves Heartburn Due To Acid Indigestion  
50 Berry Flavored Chewable Tablets

**50 Berry Flavored Chewable Tablets**

**Pepcid AC + ANTIAC = Pepcid Complete**

The acid reducer (Pepcid AC) and the antacid (AntiAC) combine to relieve heartburn associated with acid indigestion and sour stomach.

DO NOT USE IF PRINTED FOR SEAL UNDER BOTTLE CAP IS OPEN OR TORN.

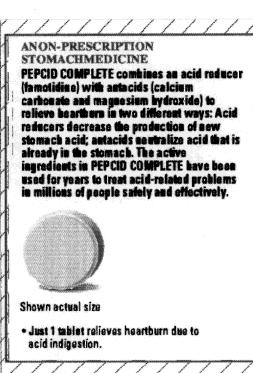
**Drug Facts**

**Active Ingredients** (in each chewable tablet) Purpose  
Famotidine 10 mg. Antacid  
Calcium carbonate 80 mg. Antacid  
Magnesium hydroxide 40 mg. Antacid

Use relieves heartburn associated with acid indigestion and sour stomach.

Questions? 1-800-755-4006  
Lift Tab for Use, Warnings, and Directions

**RESERVED FOR COUPON TEXT**



**Drug Facts (continued)**

**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 famotidine products or acid reducers  
**Ask a doctor or pharmacist before use if you are presently taking a prescription drug. Antacids may interact with certain prescription drugs.**  
**Stop use and see 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.**

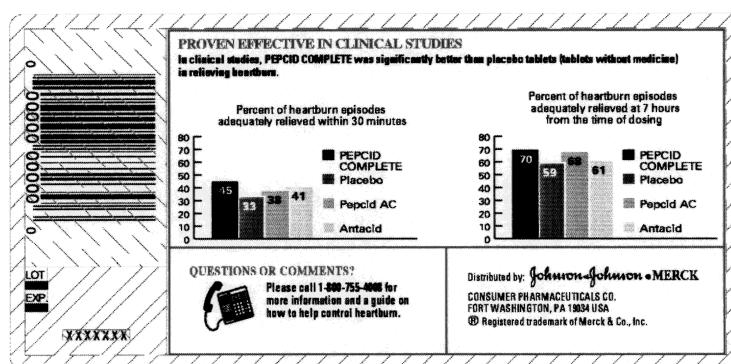
**Directions**  
 • adults and children 12 years and over:  
 - do not swallow whole; chew completely  
 - do not swallow chyme  
 - do not use more than 2 chewable tablets in 24 hours  
 • children under 12 years: ask a doctor

**Other Information**  
 • read the directions and warnings before use → keep this booklet. It contains important information.  
 • store at 25-30°C (77-86°F) → protect from moisture

**Inactive ingredients** cellulose acetate, corn starch, D&C red 7, dextrose, FD&C blue #1, FD&C red 40, flavors, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, pregelatinized starch, sodium lauryl sulfate, sugar

**Questions or comments?** call toll-free 1-800-755-4006

Shown actual size  
 \* Just 1 tablet relieves heartburn due to acid indigestion.



Labeling Format Information:	
Fonts: Univers condensed, bold	and bold italic.
Drug Facts:	9 pt
Header:	8 pt
Subheader:	8 pt
Body Text:	6 pt
Drug Facts (continued):	8 pt
Horizontal Scale: 94%	Average Kerning: -4

JOB DESCRIPTION LBLPEPCIDCOMPLETEBERRYCHEWTAB50

FILE # 300322B-1 VERSION

DATE May31,2001 LB-PS-848.0 DIE VINYL

PS IMAGE # M245/M296/ M300/LIVEART KEY CONTACT Tony Nucera

Compared By: DESIGN PROGRAM ILLUS.9er.

MAXIMUM OF FIVE COLORS PER COMPONENT

YELLOW	Cyan	Magenta	Black	KERED
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THIS DESIGN BLOCK MUST BE SAVED WITH FILE AND PRINTED ON THERMAL.

THIS BLOCK IS FOR DESIGN PURPOSES ONLY.

PRINTER: **McNeil** Johnson & Johnson • MERCK

GRAPHIC ANALYST:

UPC #:

PART NUMBER:

PCN/NPA NUMBER:

INITIALS: DATE:

FCC#:

PACKAGING LOCATION:

COLOR STANDARD:

VALIDITY DATE:

REGULATORY:

MEDICAL:

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**

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/s/

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Linda Katz  
11/6/01 03:28:29 PM