

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-393 & 21-394

APPROVED LABELING

128 code #248061

FPO

Advil PM

LIQUI-GELS

Solubilized Ibuprofen, 200 mg / Diphenhydramine HCl, 25 mg
Pain Reliever (NSAID) / Nighttime Sleep-Aid

32 Liqui-Gels®
(Liquid Filled Capsules)

128 code #248061

FPO

Drug Facts (continued)

Warnings

Advil PM (ibuprofen) may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- skin rash
- swelling of the face, lips, tongue, or throat
- difficulty breathing

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you:

- take aspirin, aspirin-like drugs, or blood thinners
- take other drugs containing an NSAID
- take any other drug containing an NSAID
- take a blood thinner (anticoagulant) or blood drug
- under a doctor's care for any condition (gastrointestinal or nonsteroidal)

Drinking alcohol while taking Advil PM may increase the risk of stomach bleeding.

Do not use Advil PM if you have had stomach ulcers or bleeding problems.

Drug Facts (continued)

Directions

Do not take more than 2 capsules in 24 hours at bedtime.

Do not take more than 12 capsules over 2 capsules in 24 hours.

Do not take longer than 10 days, unless directed by a doctor (see Warnings).

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- under a doctor's care for any condition (gastrointestinal or nonsteroidal)

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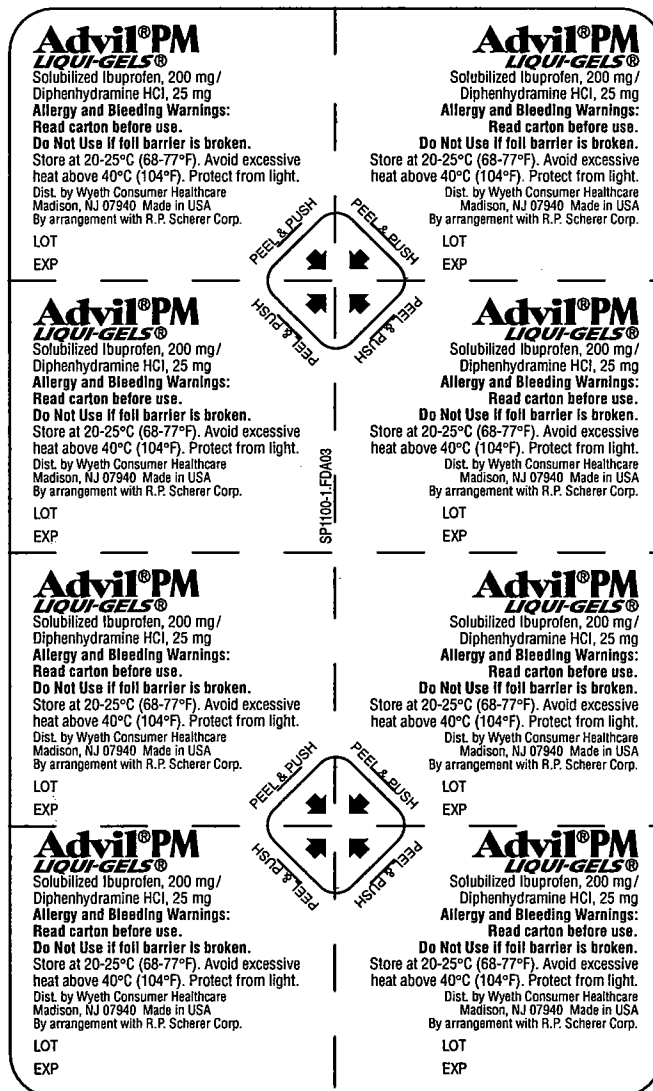
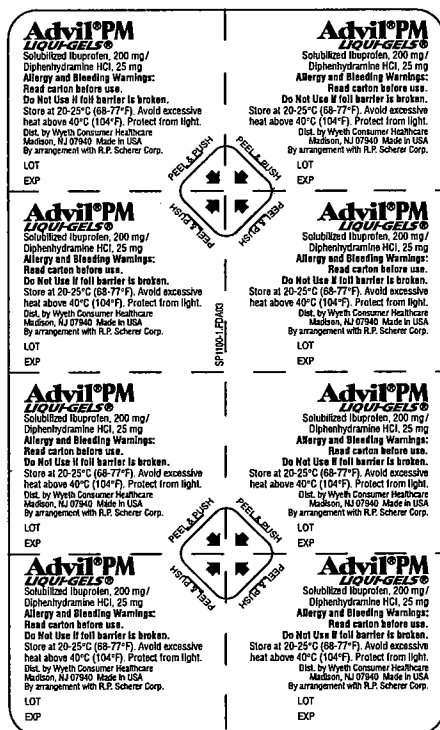
Do not use Advil PM if you have had stomach ulcers or bleeding problems.

Job Information	Color Legend
Date 12/13/05 PASS # 1 Component # UK24806-1.FDA03 Drawing # 5015 Regulatory Manuscript Version: 12/13/05 Formula # WH# 0723-0009.02	PROCESS CYAN PROCESS MAGENTA PROCESS YELLOW PROCESS BLACK PANTONE 285 C PANTONE 279 C
Identification	Printer Notes
Wyeth Consumer Healthcare Graphics Development & Labeling Compliance Five Glinda Farms, Madison, NJ 07940 Phone: (973) 660-5000 • Fax: (973) 660-6048	Printer to Replace all FPO Codes with Scannable Art PILL SOFT DROP SHADOW TO PRINT PROCESS BLACK.
Vendor Identification	
Graphics Development & Labeling Compliance Graphic Artist: Jeffrey M. Caruso SC: 12/13/05	

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

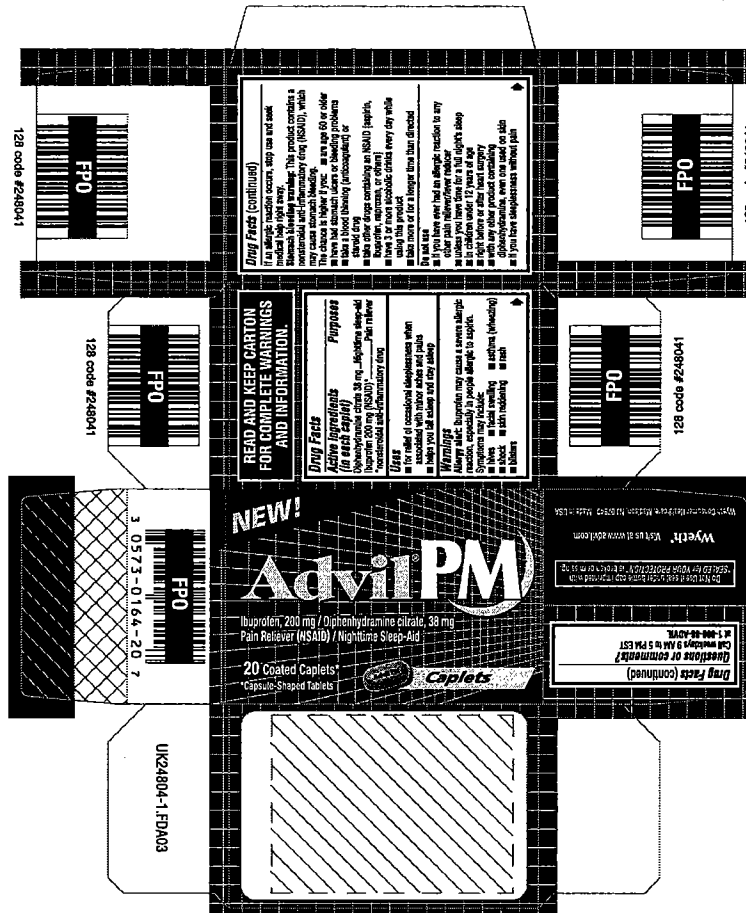
150% FOR PROOFREADING

ACTUAL SIZE



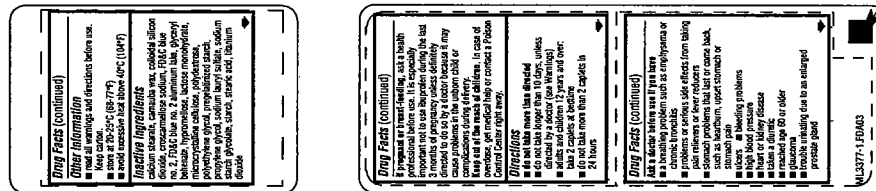
Job Information	Color Legend
Date 12/13/05 PASS # 1 Component # SP1100-1.FDA03 Drawing # 5007 Regulatory Manuscript Version: 12/13/05 Formula # WH# 0723-0009	 PANTONE 282 C
Identification	Printer Notes
Wyeth Consumer Healthcare Graphics Development & Labeling Compliance Five Giralda Farms, Madison, NJ 07940 Phone: (973) 660-5000 • Fax: (973) 660-6048	Printer to Replace all FPO Codes with Scannable Art
Vendor Identification	
Graphics Development & Labeling Compliance Graphic Artist: Jeffrey M. Caruso SC: 12/13/05	

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	N/A
• SUBHEADINGS/BODY TEXT	4 pt
• LEADING	4.3 pt
• BULLETS	N/A
• SPACE BEFORE BULLET	N/A
• WARNING BOX LINE, HAIRLINES	N/A



Job Information	Color Legend
Date 12/13/05 PASS # 1 Component # UK24804-1.FDA03 Drawing # 6208 Rev. # 1 Regulatory Manuscript Version: 12/13/05 Formula # FLF# 0555-0008.00	 PROCESS CYAN PROCESS MAGENTA PANTONE 282 C PROCESS YELLOW PROCESS BLACK PANTONE 270 C
Identification	Printer Notes
Wyeth Consumer Healthcare Graphics Development & Labeling Compliance Five Girardeau Farms, Madison, NJ 07940 Phone: (873) 660-5000 • Fax: (873) 660-6048	Printer to Replace all FPO Codes with Scannable Art PILL SOFT DROP SHADOW TO PRINT PROCESS BLACK.
Vendor Identification	
Graphics Development & Labeling Compliance Graphic Artist: Jeffrey M. Caruso SC: 12/13/05	

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces



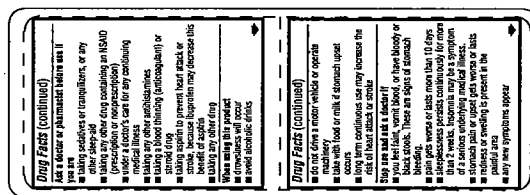
BASE PANEL

PANEL #4

PANEL #1

3/16" X 3/16" DATA MATRIX
CODE (ECC 200), PRINTED
IN BLACK OR DARK BLUE
ON UNPRINTED WHITE
BACKGROUND.

DATA MATRIX
CODE = 337701



PANEL #2

PANEL #3

Job Information	Color Legend
Date 12/13/05 PASS # 1 Component # ML3377-1.FDA03 Drawing # 6211 Rev. # 1 Regulatory Manuscript Version: 12/13/05 Formula # FLF# 0555-0008.00	
Identification	Printer Notes
Wyeth Consumer Healthcare Graphics Development & Labeling Compliance Five Girardin Farms, Madison, NJ 07940 Phone: (973) 660-5000 • Fax: (973) 660-6048	Printer to Replace all FPO Codes with Scannable Art
Vendor Identification	
Graphics Development & Labeling Compliance Graphic Artist: Jeffrey M. Caruso SC: 12/13/05	

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	N/A
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	N/A
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

ACTUAL SIZE



UNVARNISHED
UNPRINTED
AREA FOR LOT
& EXP.

3/16" X 3/16" DATA MATRIX
CODE (ECC 200), PRINTED
IN BLACK OR DARK BLUE
ON UNPRINTED WHITE
BACKGROUND.

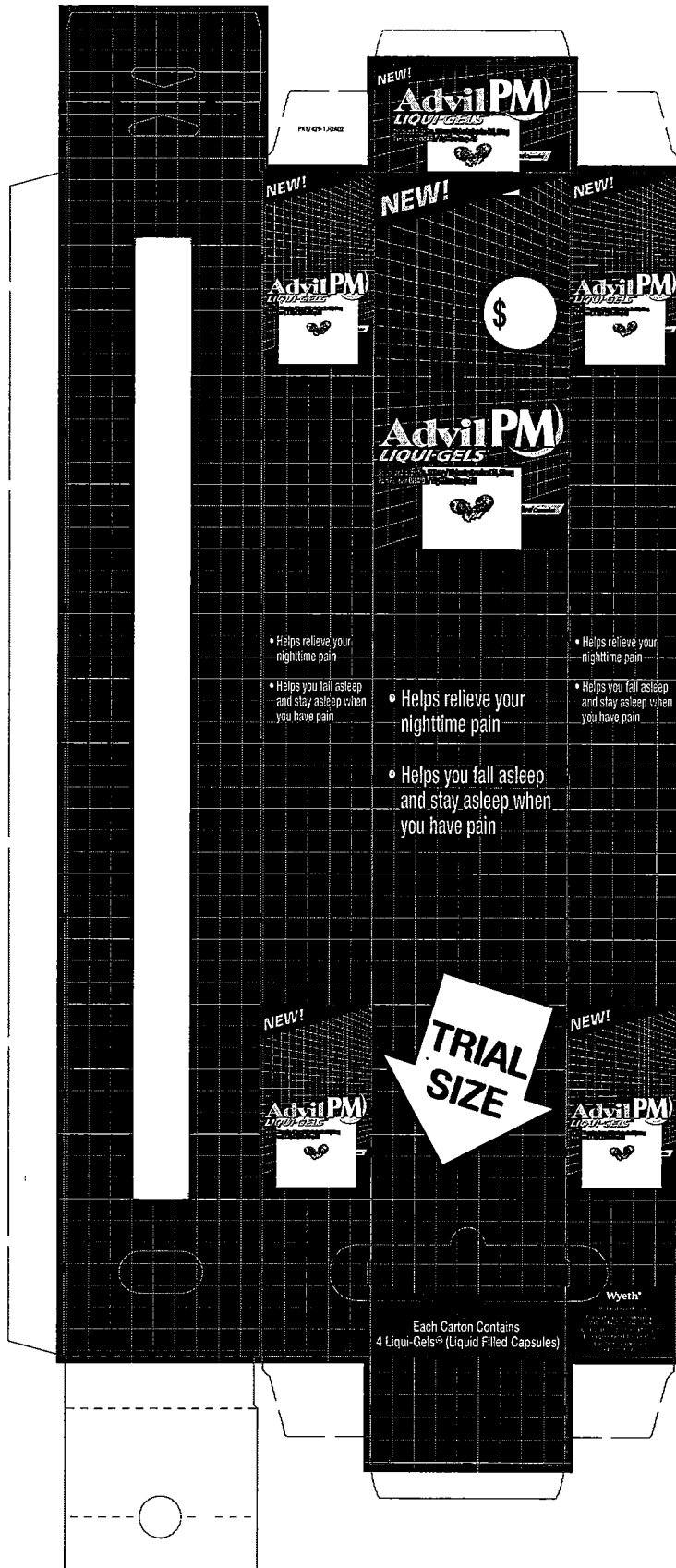
DATA MATRIX
CODE = 01642001

150% FOR PROOFREADING



Job Information	Color Legend
Date 12/13/05 PASS # 3 Component # U0164-20-1.FDA03 Drawing # 5514 Regulatory Manuscript Version: 12/13/05 Formula # WH# 0555-0008	PANTONE 285 C
Identification	
Wyeth Consumer Healthcare Graphics Development & Labeling Compliance Five Giraffe Farms, Madison, NJ 07940 Phone: (973) 660-5000 • Fax: (973) 660-6048	PROCESS YELLOW
Vendor Identification	
Graphics Development & Labeling Compliance Graphic Artist: Jeffrey M. Caruso SC: 12/13/05	Printer Notes Printer to Replace all FPO Codes with Scannable Art

DRUG FACTS TEXT DERIVED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADINGS/BODY TEXT	4.5 pt
• LEADING	4.5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINES	.5 pt



Job Information	Color Legend
Date: 12/14/05 Version: 1.0 Prepared by: [Name] Reviewed by: [Name] Approved by: [Name]	[Color Swatch] PROCESS BLACK [Color Swatch] PROCESS WHITE [Color Swatch] PROCESS YELLOW [Color Swatch] PROCESS MAGENTA [Color Swatch] PROCESS CYAN
Wyeth Consumer Healthcare 400 North Zeeb Road P.O. Box 1000 Kenilworth, NJ 07033	[Color Swatch] PROCESS BLACK [Color Swatch] PROCESS WHITE [Color Swatch] PROCESS YELLOW [Color Swatch] PROCESS MAGENTA [Color Swatch] PROCESS CYAN
Vendor Information Wyeth Consumer Healthcare 400 North Zeeb Road P.O. Box 1000 Kenilworth, NJ 07033	Printer: [Name] 400 North Zeeb Road P.O. Box 1000 Kenilworth, NJ 07033 FILL SOFT COPY SHADOW TO PRINT PROCESS BLACK

- 50 Packets of 2 Caplets***
*Capsule-Shaped Tablets

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	N/A
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	0.5 pt
• # OF CHARACTERS PER INCH	<19
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARRIQUES, HAIRLINES	1.5 pt, 5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Formulario de Registro de la Actividad de la Empresa Formulario de Registro de la Actividad de la Empresa	
1. Nombre de la Empresa:	
2. Domicilio:	
3. Fecha de Inicio de la Actividad:	
4. Tipo de Actividad:	
5. Descripción de la Actividad:	
6. Nombre del Representante Legal:	
7. Domicilio del Representante Legal:	
8. Fecha de Emisión:	
9. Lugar de Emisión:	
10. Observaciones:	
11. Firma del Representante Legal:	
12. Firma del Emisor:	
13. Fecha de Validación:	
14. Lugar de Validación:	
15. Observaciones:	
16. Firma del Representante Legal:	
17. Firma del Emisor:	
18. Fecha de Validación:	
19. Lugar de Validación:	
20. Observaciones:	
21. Firma del Representante Legal:	
22. Firma del Emisor:	
23. Fecha de Validación:	
24. Lugar de Validación:	
25. Observaciones:	
26. Firma del Representante Legal:	
27. Firma del Emisor:	
28. Fecha de Validación:	
29. Lugar de Validación:	
30. Observaciones:	
31. Firma del Representante Legal:	
32. Firma del Emisor:	
33. Fecha de Validación:	
34. Lugar de Validación:	
35. Observaciones:	
36. Firma del Representante Legal:	
37. Firma del Emisor:	
38. Fecha de Validación:	
39. Lugar de Validación:	
40. Observaciones:	
41. Firma del Representante Legal:	
42. Firma del Emisor:	
43. Fecha de Validación:	
44. Lugar de Validación:	
45. Observaciones:	
46. Firma del Representante Legal:	
47. Firma del Emisor:	
48. Fecha de Validación:	
49. Lugar de Validación:	
50. Observaciones:	
51. Firma del Representante Legal:	
52. Firma del Emisor:	
53. Fecha de Validación:	
54. Lugar de Validación:	
55. Observaciones:	
56. Firma del Representante Legal:	
57. Firma del Emisor:	
58. Fecha de Validación:	
59. Lugar de Validación:	
60. Observaciones:	
61. Firma del Representante Legal:	
62. Firma del Emisor:	
63. Fecha de Validación:	
64. Lugar de Validación:	
65. Observaciones:	
66. Firma del Representante Legal:	
67. Firma del Emisor:	
68. Fecha de Validación:	
69. Lugar de Validación:	
70. Observaciones:	
71. Firma del Representante Legal:	
72. Firma del Emisor:	
73. Fecha de Validación:	
74. Lugar de Validación:	
75. Observaciones:	
76. Firma del Representante Legal:	
77. Firma del Emisor:	
78. Fecha de Validación:	
79. Lugar de Validación:	
80. Observaciones:	
81. Firma del Representante Legal:	
82. Firma del Emisor:	
83. Fecha de Validación:	
84. Lugar de Validación:	
85. Observaciones:	
86. Firma del Representante Legal:	
87. Firma del Emisor:	
88. Fecha de Validación:	
89. Lugar de Validación:	
90. Observaciones:	
91. Firma del Representante Legal:	
92. Firma del Emisor:	
93. Fecha de Validación:	
94. Lugar de Validación:	
95. Observaciones:	
96. Firma del Representante Legal:	
97. Firma del Emisor:	
98. Fecha de Validación:	
99. Lugar de Validación:	
100. Observaciones:	

NEW!

Sample – Not For Sale

Advil[®] PM

(ibuprofen, 200 mg) / Diphenhydramine HCl, 25 mg
Pain Reliever (NSAID) / Nighttime Sleep Aid



Tablets

Box contains 2 Capsules
Capsule-Shaped Tablets

[illegible]

30 Buckets of 2 Caplets*
*Capsule-Shaped Tablets

NEW!

Sample - Not For Sale

Advil[®] PM

Luncheon, Dinner / Oatmeal
Pain Reliever (NSAID) / Sleep Aid

 Let's

© 2004 Pfizer Inc. All rights reserved.

- 50 Packets of 2 Caplets***
*Capsule-Shaped Tablets

Caplets are crushed in a pill crusher or ground with
Do not use if the caplet is broken or soft.

NEW!

Sample – Not For Sale

Advil^{PM}

Dosage: 200 mg / Dicyclanil 10 mg / Zolpidem 35 mg

Pain Reliever (NSAID) / Nighttime Sleep Aid

Advil^{PM}

- 50 Packets of 2 Caplets***
*Capsule-Shaped Tablets

Wyeth Division of Wyeth Pharmaceuticals, Inc.

PHARMACODE FPO
16G711