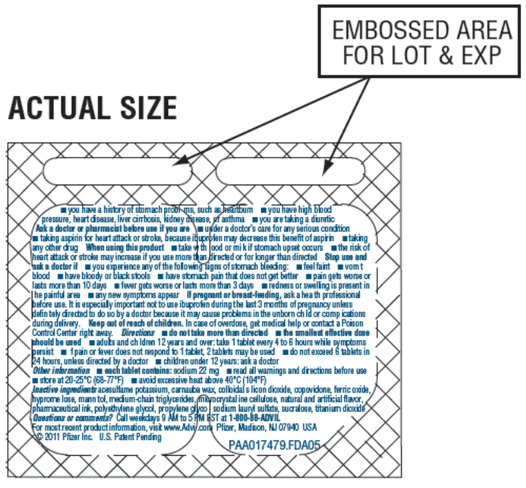
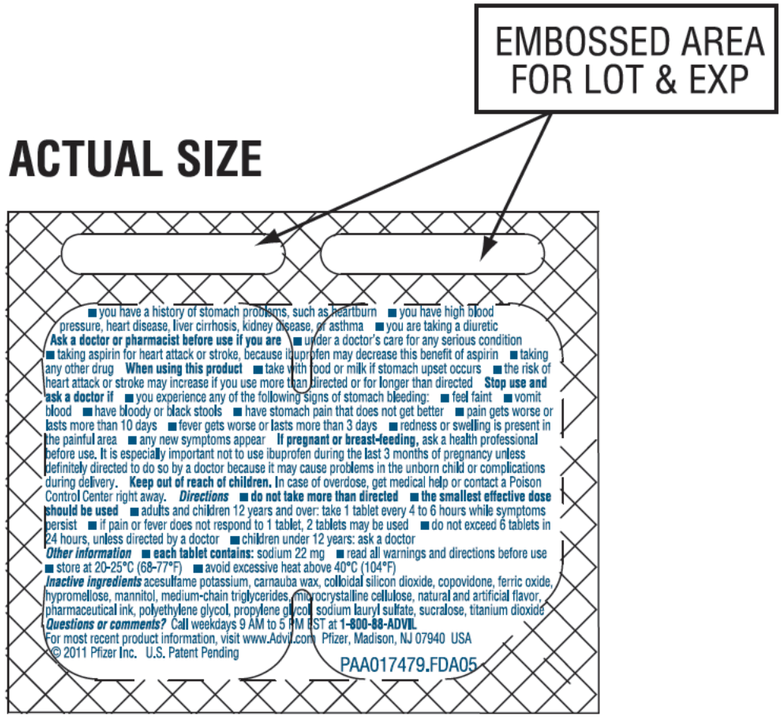
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201803Orig1s000

LABELING





(b) (4)

DRUG FACTS TEXT DEFINED	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 LINE, HAIRLINES	N/A

DEPARTMENT	REVIEWED BY PRINT NAME	SIGNATURE	DATE	✔ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

RELEASED

Name _____ Date _____

ACTUAL SIZE

(b) (4)

ACTUAL SIZE

(b) (4)

(b) (4)

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
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• LEADING	4.5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE, HAIRLINES	N/A

DEPARTMENT	REVIEWED BY PRINT NAME	REVIEWED BY SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

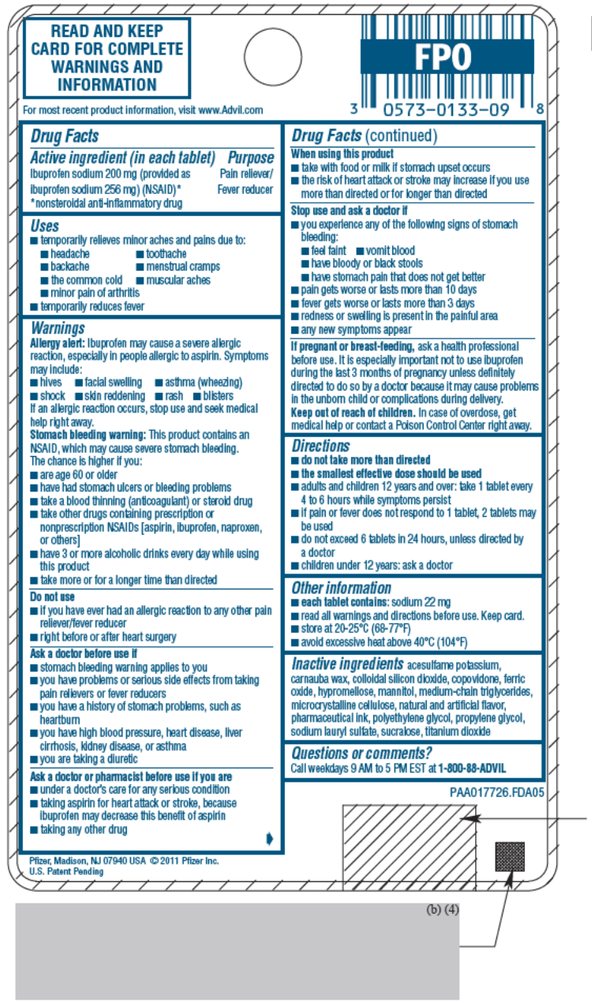
RELEASED

Name _____ Date _____

FRONT

1/8" Clear area around Data Matrix - Unprinted

BACK



UNPRINTED AREA FOR ANACIN FOR LOT & EXP.
PRINTED AREA FOR ADVIL LOT & EXP

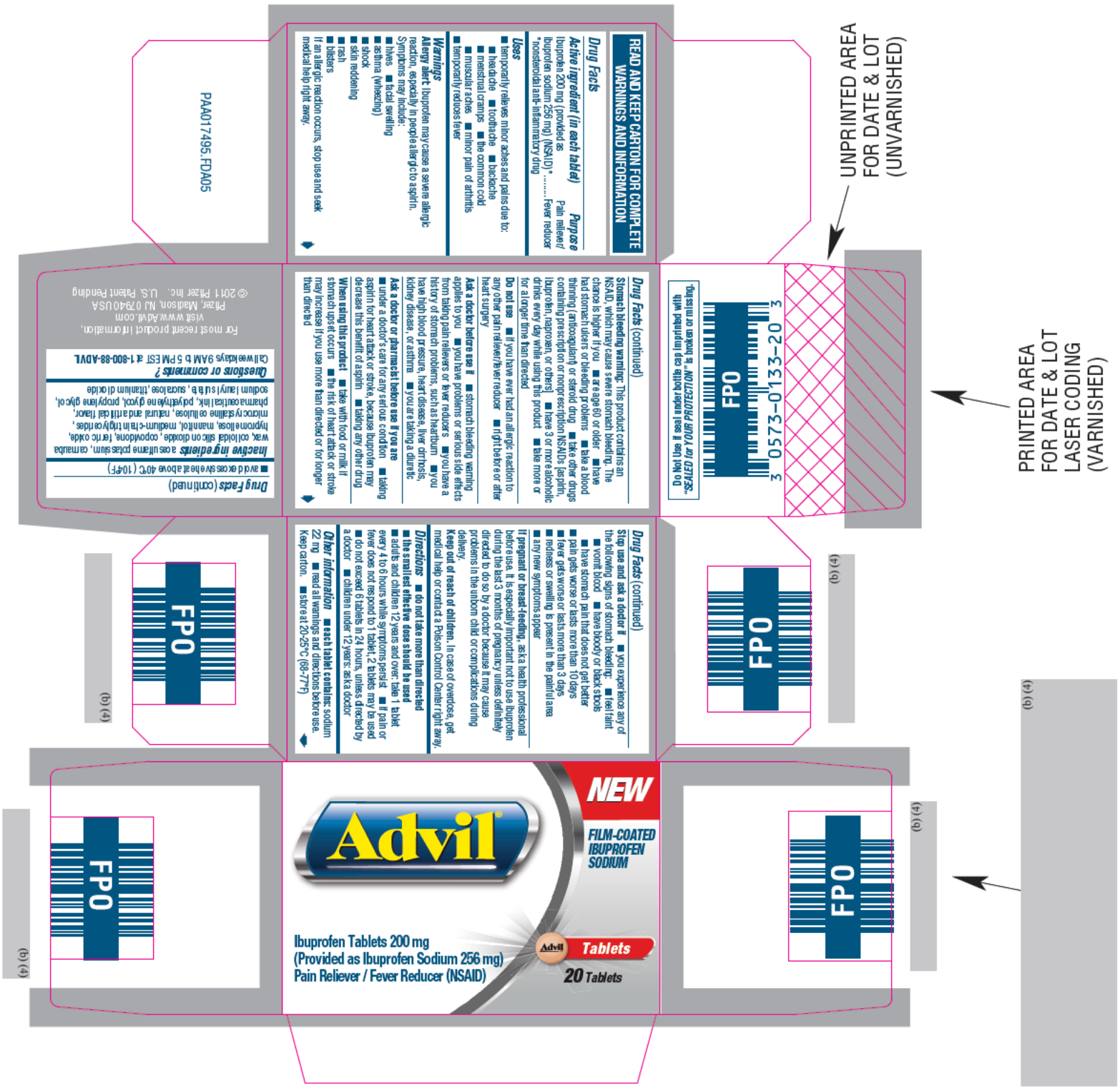
(b) (4)

DEPARTMENT	REVIEWED BY PRINT NAME	REVIEWED BY SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

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	6.25 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

RELEASED

Name _____ Date _____



DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	8 pt
• DRUG FACTS CONTINUED	7 pt
• HEADINGS	7 pt
• SUBHEADINGS/BODY TEXT	6 pt
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DEPARTMENT	REVIEWED BY PRINT NAME	SIGNATURE	DATE	✔ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

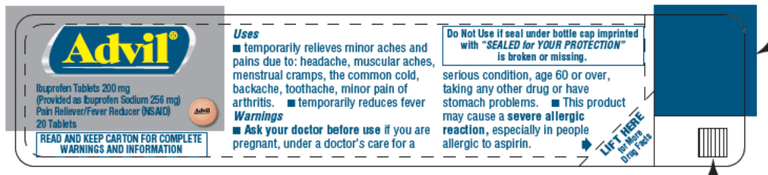
(b) (4)

RELEASED

Name _____ Date _____

Reference ID: 2938899

Actual Size

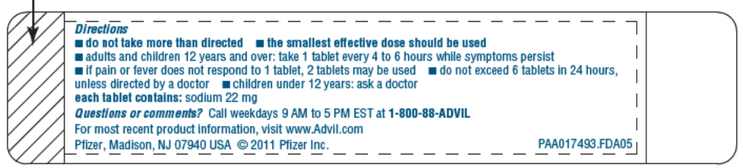


TOP

UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE. FOR LOT & EXPIRATION AREA

(b) (4)

3/8" HINGE AREA UNVARNISHED



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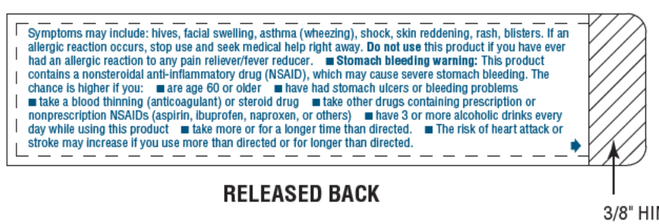
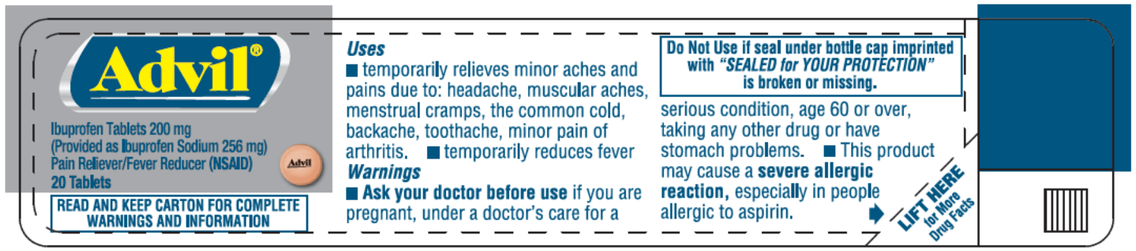


RELEASED BACK

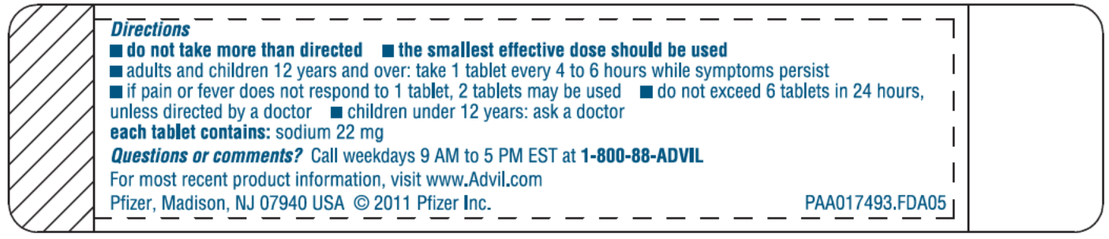
3/8" HINGE AREA UNVARNISHED

(b) (4)

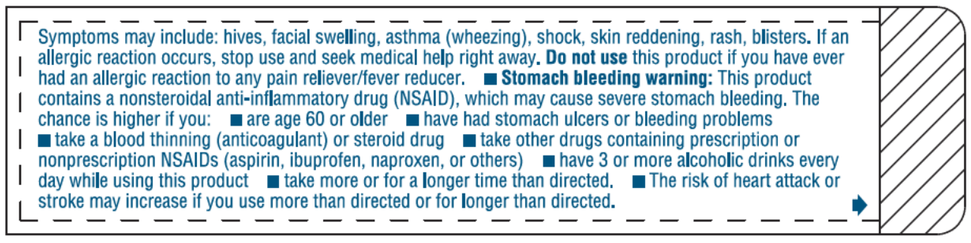
150%



TOP



BASE



RELEASED BACK

(b) (4)

DEPARTMENT	REVIEWED BY PRINT NAME	REVIEWED BY SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE, HAIRLINES	.5 pt

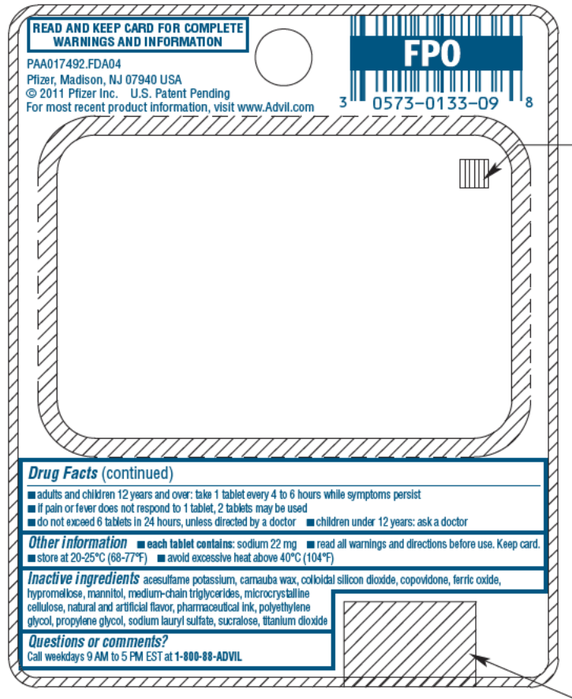
RELEASED

Name _____ Date _____

FRONT

(b) (4)

BACK



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Labeling Compliance				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

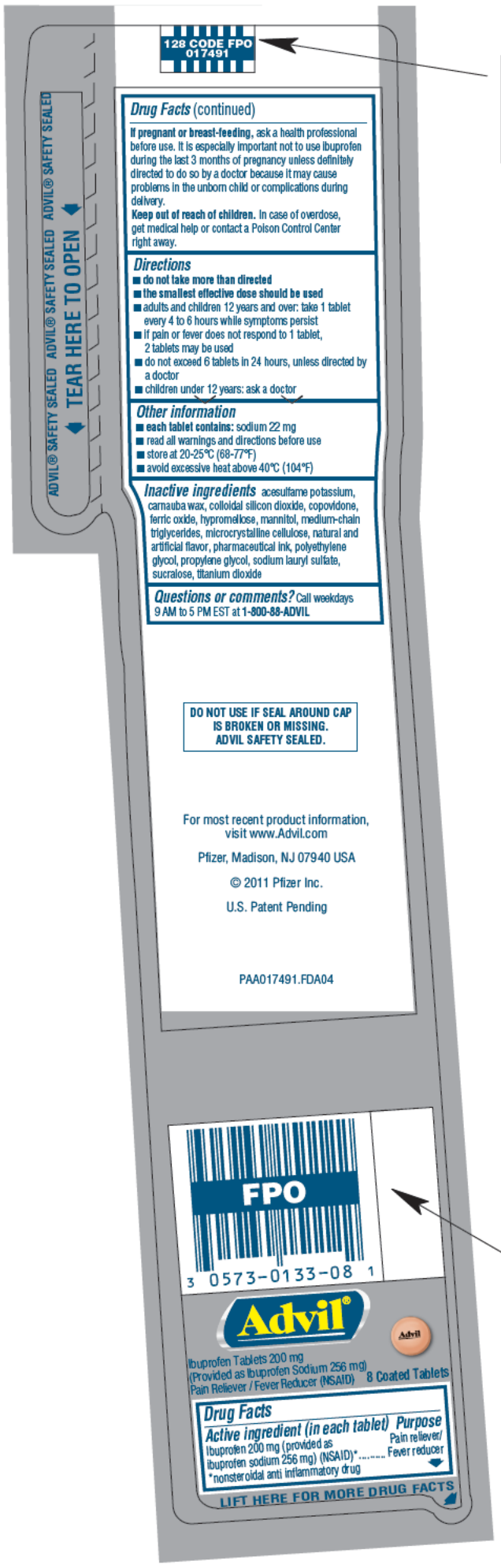
DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	N/A
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

RELEASED

Name _____ Date _____

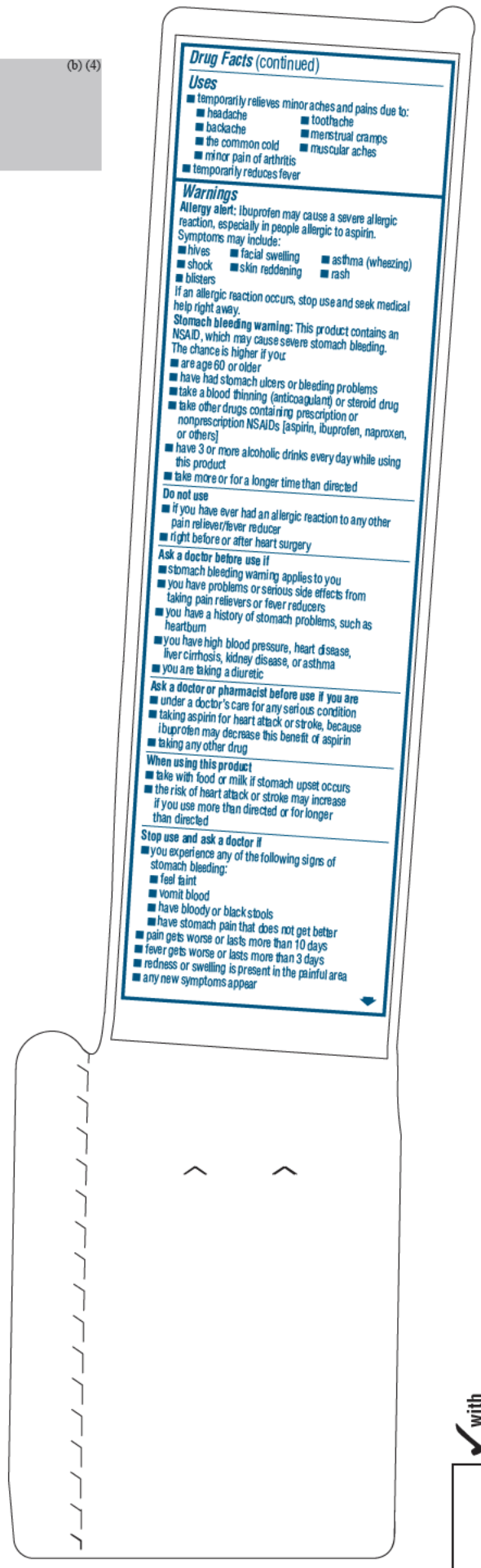
OUTSIDE

INSIDE



(b) (4)

UNVARNISHED AREA FOR LOT AND EXP. DATE



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(b) (4)

DEPARTMENT	REVIEWED BY: PRINT NAME	REVIEWED BY: SIGNATURE	✓ with Changes / DATE
Graphic Artist			
Labeling Compliance			
Packaging Engineer			
Medical			
Regulatory Affairs			
Marketing			
Legal			
Trademark			
Display Services			
Promotions			
Graphic Artist Closed			

RELEASED

Name _____ Date _____

Reference ID: 2938899

(4) (a)

128 CODE FPO 017480

Drug Facts

Active Ingredient (in each tablet) — Purpose

Ibuprofen 200 mg (provided as ibuprofen sodium 256 mg (NSAID)) * ..... Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - toothache
  - backache
  - menstrual cramps
  - the common cold
  - muscular aches
  - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

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

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver disease, kidney disease, or asthma
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- you get symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness on one side
  - slurred speech
- you get these symptoms of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- you get these symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness on one side
  - slurred speech
- headache worsens or lasts more than 3 days
- you get symptoms that could be signs of a serious disease
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

Directions

- do not take more than directed
- adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

the smallest effective dose should be used	

Other information

- each tablet contains: sodium 22 mg
- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

acesulfame potassium, carnauba wax, colloidal silicon dioxide, copovidone, ferric oxide, hypromellose, magnesium stearate, microcrystalline cellulose, natural and artificial flavor, polyethylene glycol, propylene glycol, sodium lauryl sulfate, sucralose, titanium dioxide

Questions or comments? Call weekdays 9 AM to 5 PM EST at 1-800-88-ADVIL

Do Not Use if the sealed child resistant pouch is broken or torn.

Pfizer, Madison, NJ 07940 USA © 2011 Pfizer Inc. U.S. Patent Pending For most recent product information, visit www.Advil.com

PAA017480.FDA04

NEW

Advil®

FILM-COATED IBUPROFEN SODIUM

Ibuprofen Tablets 200 mg
(Provided as Ibuprofen Sodium 256 mg)
Pain Reliever / Fever Reducer (NSAID)

Advil Tablets

- ☑ Headache
- ☑ Muscular Aches
- ☑ Minor Pain of Arthritis
- ☑ Menstrual Cramps
- ☑ Toothache
- ☑ Fever

50 PACKETS OF 2 COATED TABLETS EACH

NEW
Advil®
Ibuprofen Tablets 200 mg
(Provided as Ibuprofen Sodium 256 mg)
Pain Reliever / Fever Reducer (NSAID)
Advil Tablets

- ☑ Headache
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- ☑ Toothache
- ☑ Muscular Aches
- ☑ Menstrual Cramps
- ☑ Fever

50 PACKETS OF 2 COATED TABLETS EACH
See Full Drug Facts information on the back of this dispenser

NEW
Advil®
Ibuprofen Tablets 200 mg
(Provided as Ibuprofen Sodium 256 mg)
Pain Reliever / Fever Reducer (NSAID)
Advil Tablets

UNVARNISHED AREA FOR LOT & EXP

- ☑ Headache
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- ☑ Minor Pain of Arthritis
- ☑ Menstrual Cramps
- ☑ Toothache
- ☑ Fever

50 PACKETS OF 2 COATED TABLETS EACH

FPO
3 0573-0133-02 9

(b) (4)

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	N/A
• HEADINGS	8 pt
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• LEADING	6.5 pt
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• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

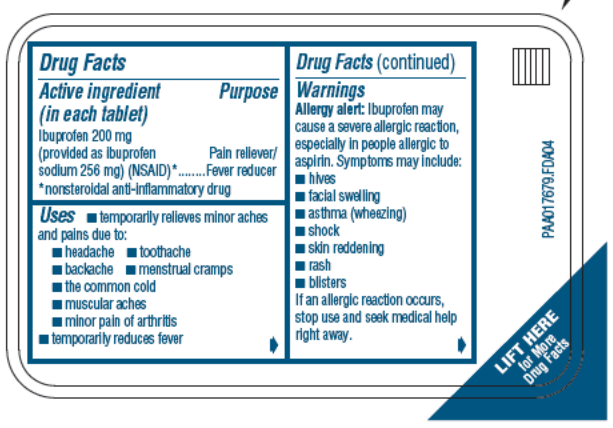
DEPARTMENT	REVIEWED BY: PRINT NAME	SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

RELEASED

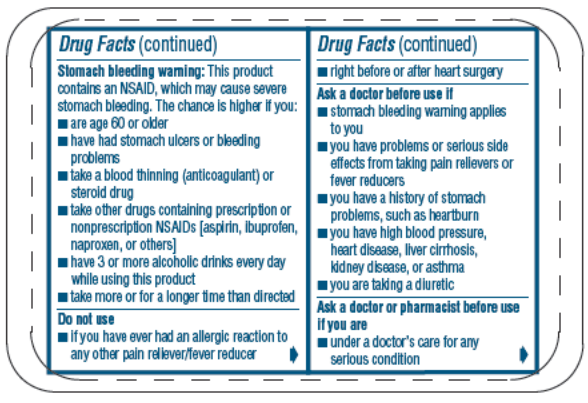
Name _____ Date _____

Reference ID: ~~2938090~~

(b) (4)



PANEL 1



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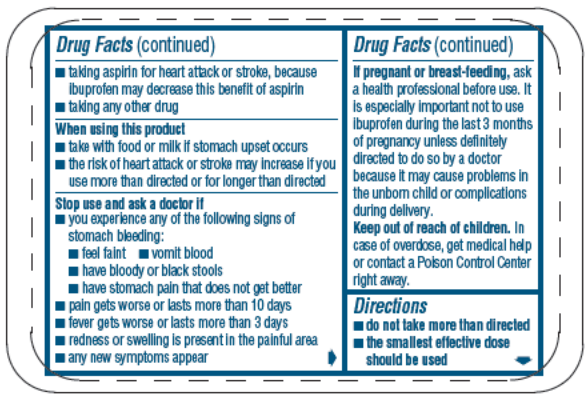

BASE PANEL

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• DRUG FACTS TITLE	9 pt
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(b) (4)

RELEASED

Name _____ Date _____

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Labeling Compliance				☐
Packaging Engineer				☐
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Regulatory Affairs				☐
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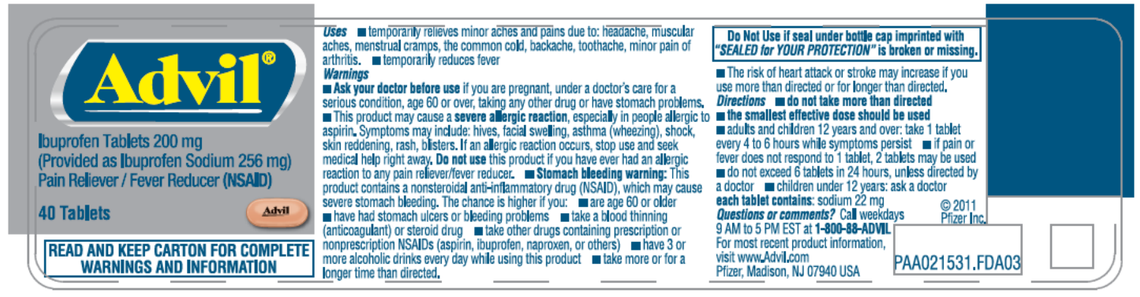
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

ACTUAL SIZE

UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE. FOR LOT & EXPIRATION AREA

150%



(b) (4)

DRUG FACTS TEXT DEFINED	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 LINE, HAIRLINES	.5 pt

DEPARTMENT	REVIEWED BY: PRINT NAME	REVIEWED BY: SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
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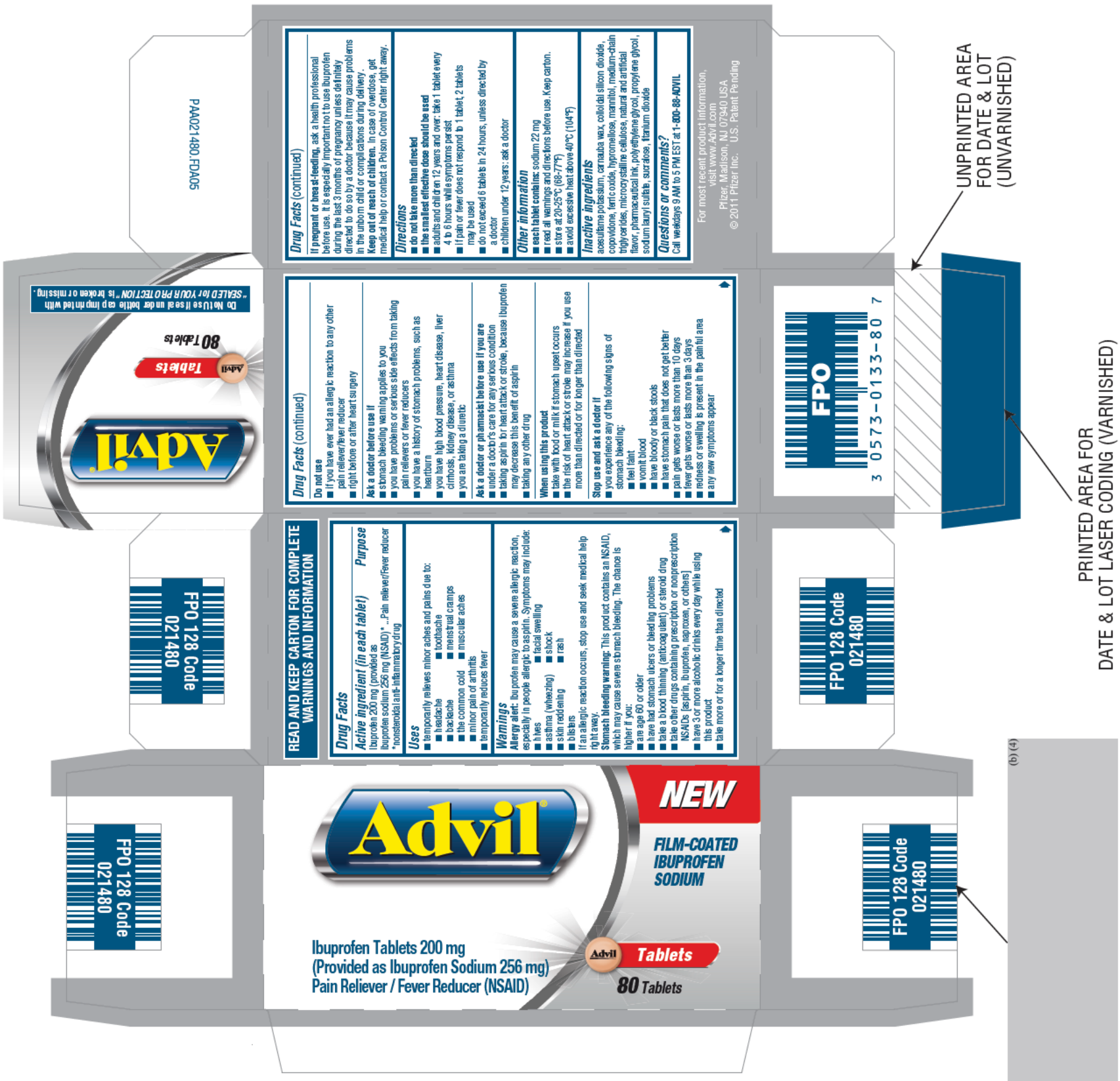
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

RELEASED

Name _____ Date _____



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Graphic Artist Closed				☐

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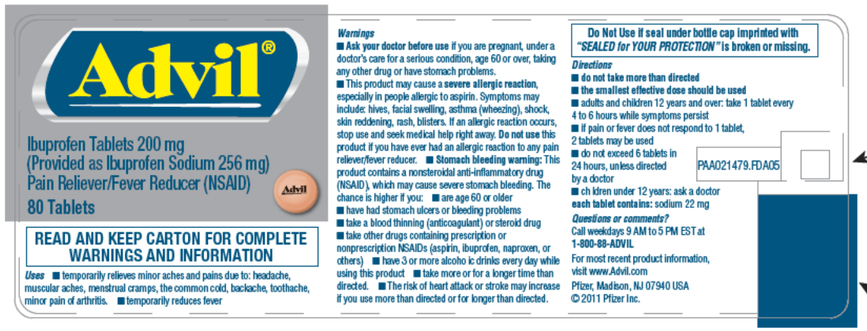
• WARNING BOX LINES	.5 pt



(b) (4)

UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE. FOR LOT & EXPIRATION AREA

(b) (4)

RELEASED

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Display Services				☐
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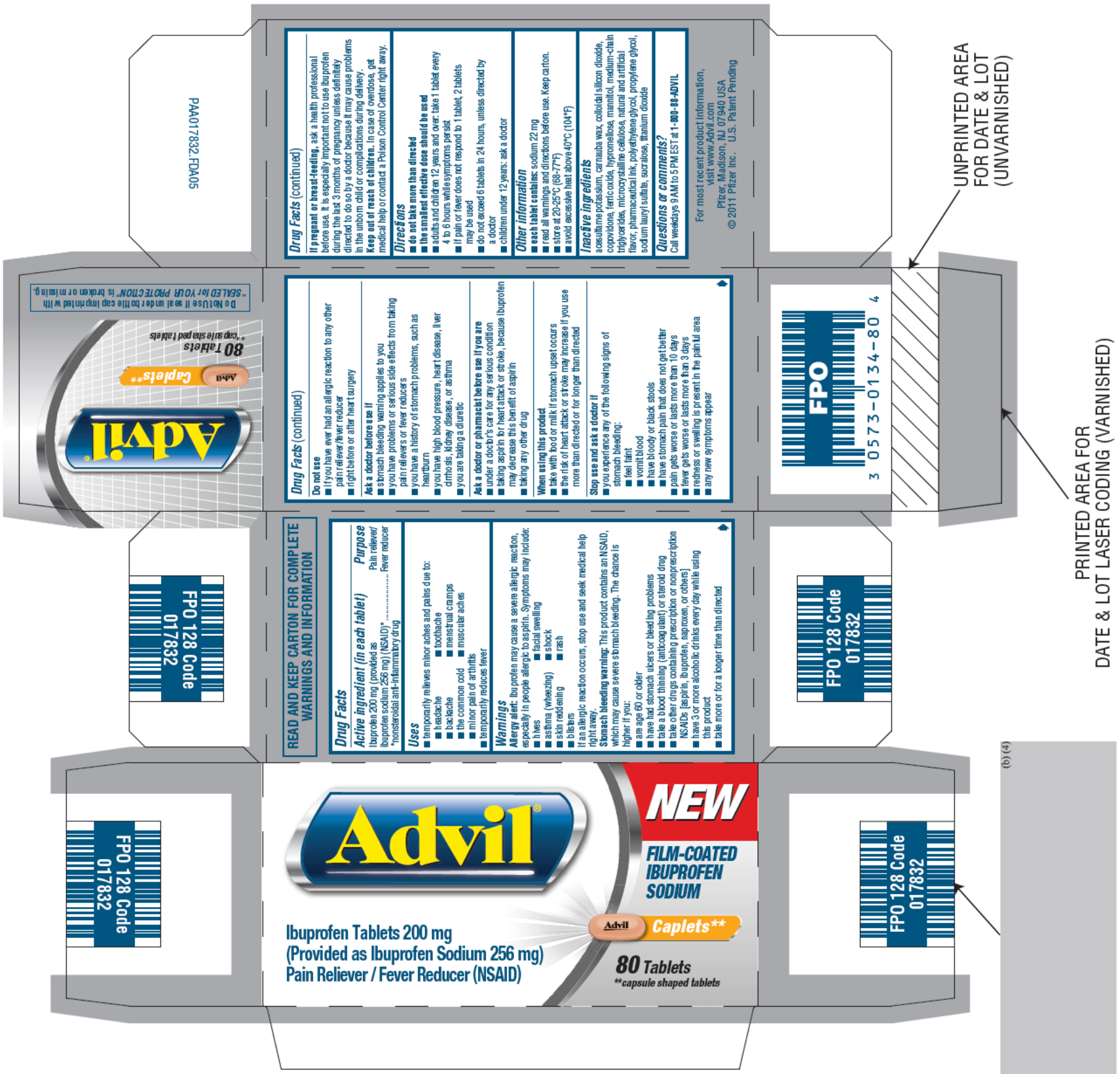
Graphic Artist Closed				☐



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• WARNING BOX LINES	.5 pt

(b) (4)

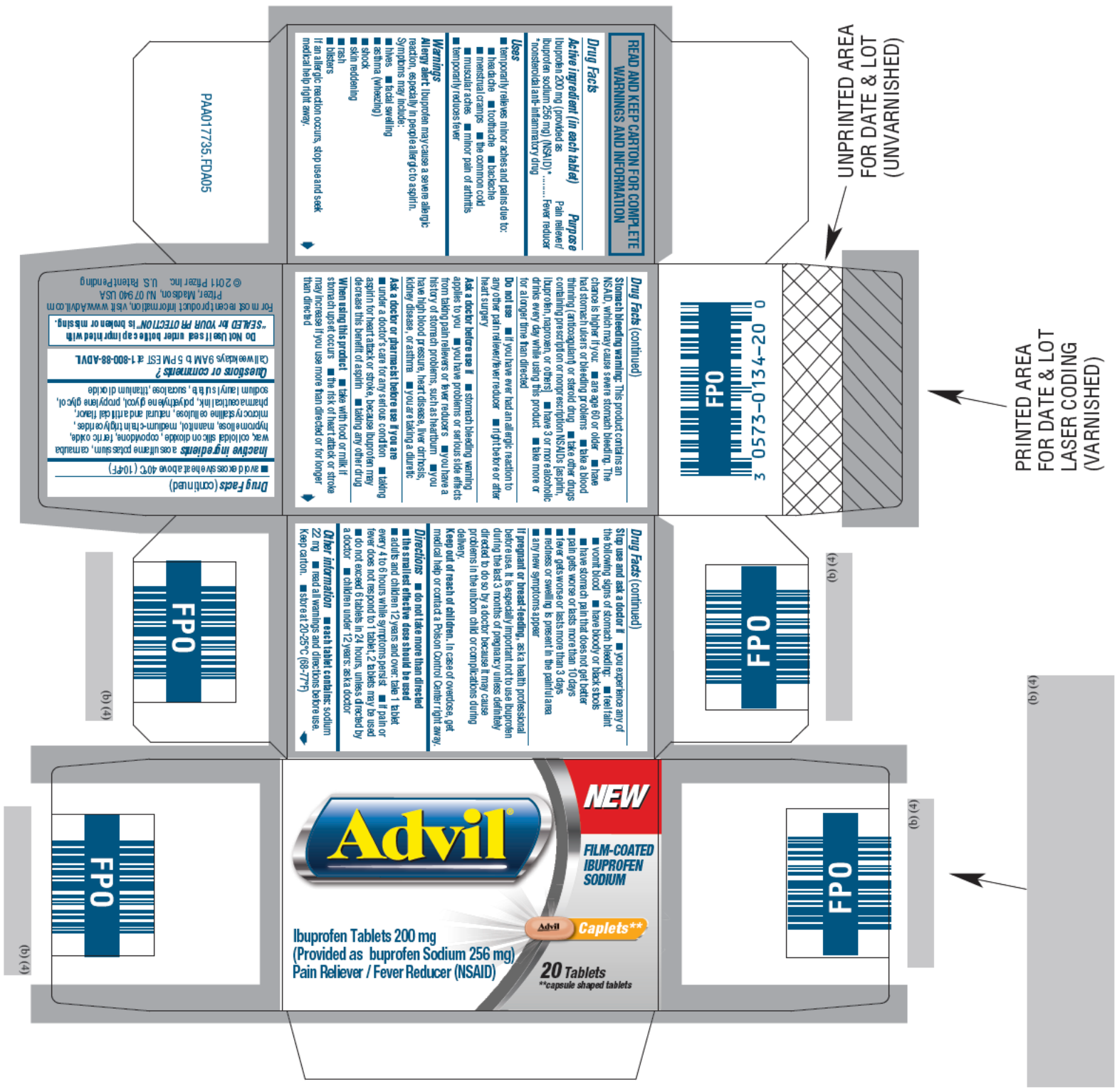
UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE. FOR LOT & EXPIRATION AREA

(b) (4)

RELEASED

Name _____ Date _____

DEPARTMENT	REVIEWED BY: PRINT NAME	REVIEWED BY: SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐



DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	8 pt
• DRUG FACTS CONTINUED	7 pt
• HEADINGS	7 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.25 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

DEPARTMENT	REVIEWED BY PRINT NAME	SIGNATURE	DATE	✔ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

(b) (4)

RELEASED

Name _____ Date _____

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE, HAIRLINES	.5 pt

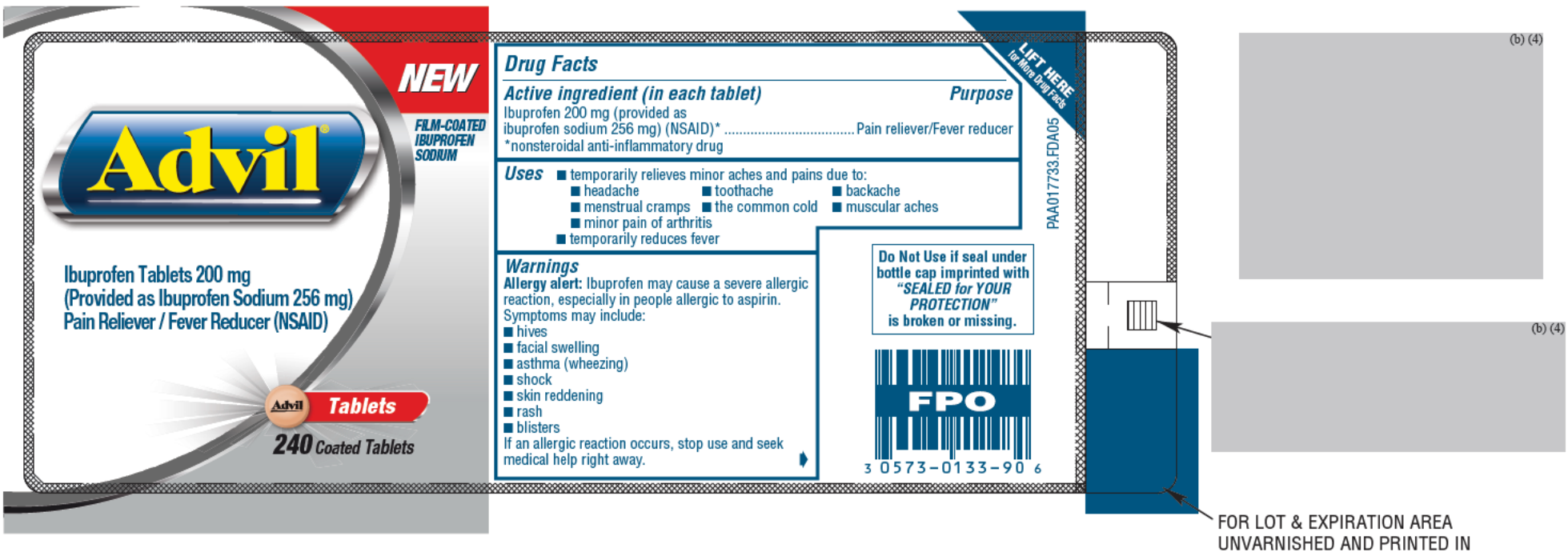
DEPARTMENT	REVIEWED BY PRINT NAME	REVIEWED BY SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

(b) (4)

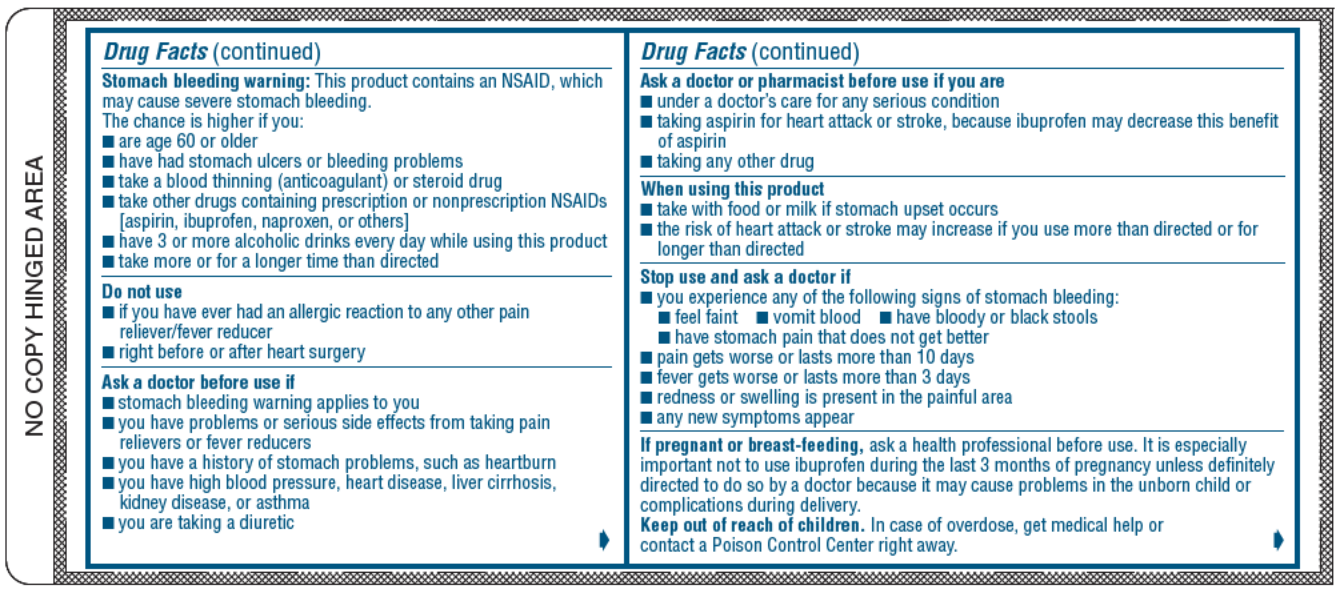
RELEASED

Name _____ Date _____

TOP LAYER FACE



TOP LAYER BACK



(b) (4)

BASE LAYER

(b) (4)

DRUG FACTS MODIFIED TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	10 pt
• DRUG FACTS CONTINUED	9 pt
• HEADINGS	9 pt
• SUBHEADINGS/BODY TEXT	7 pt
• LEADING	7.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	6 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

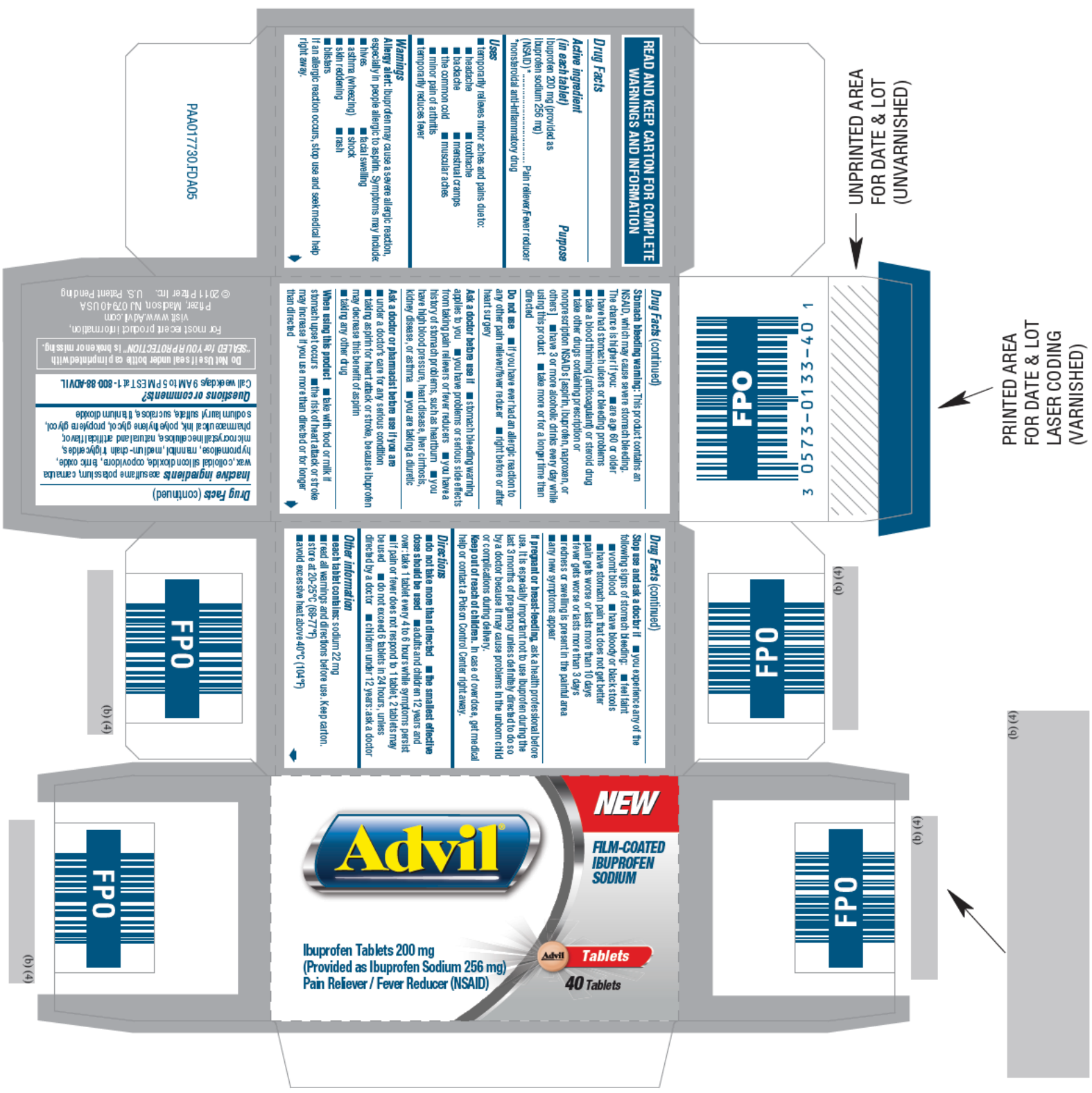
(b) (4)

Refer

RELEASED

Name _____ Date _____

DEPARTMENT	REVIEWED BY PRINT NAME	REVIEWED BY SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐



DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	8 pt
• DRUG FACTS CONTINUED	7 pt
• HEADINGS	7 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

(b) (4)

RELEASED

Name _____ Date _____

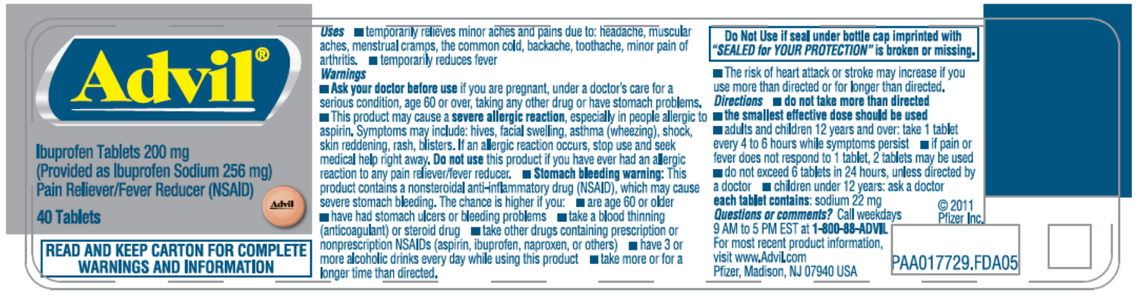
DEPARTMENT	REVIEWED BY: PRINT NAME	REVIEWED BY: SIGNATURE	DATE	✓ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

ACTUAL SIZE

UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE. FOR LOT & EXPIRATION AREA

(b) (4)

150%



DRUG FACTS TEXT DEFINED	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 LINE, HAIRLINES	.5 pt

(b) (4)

RELEASED

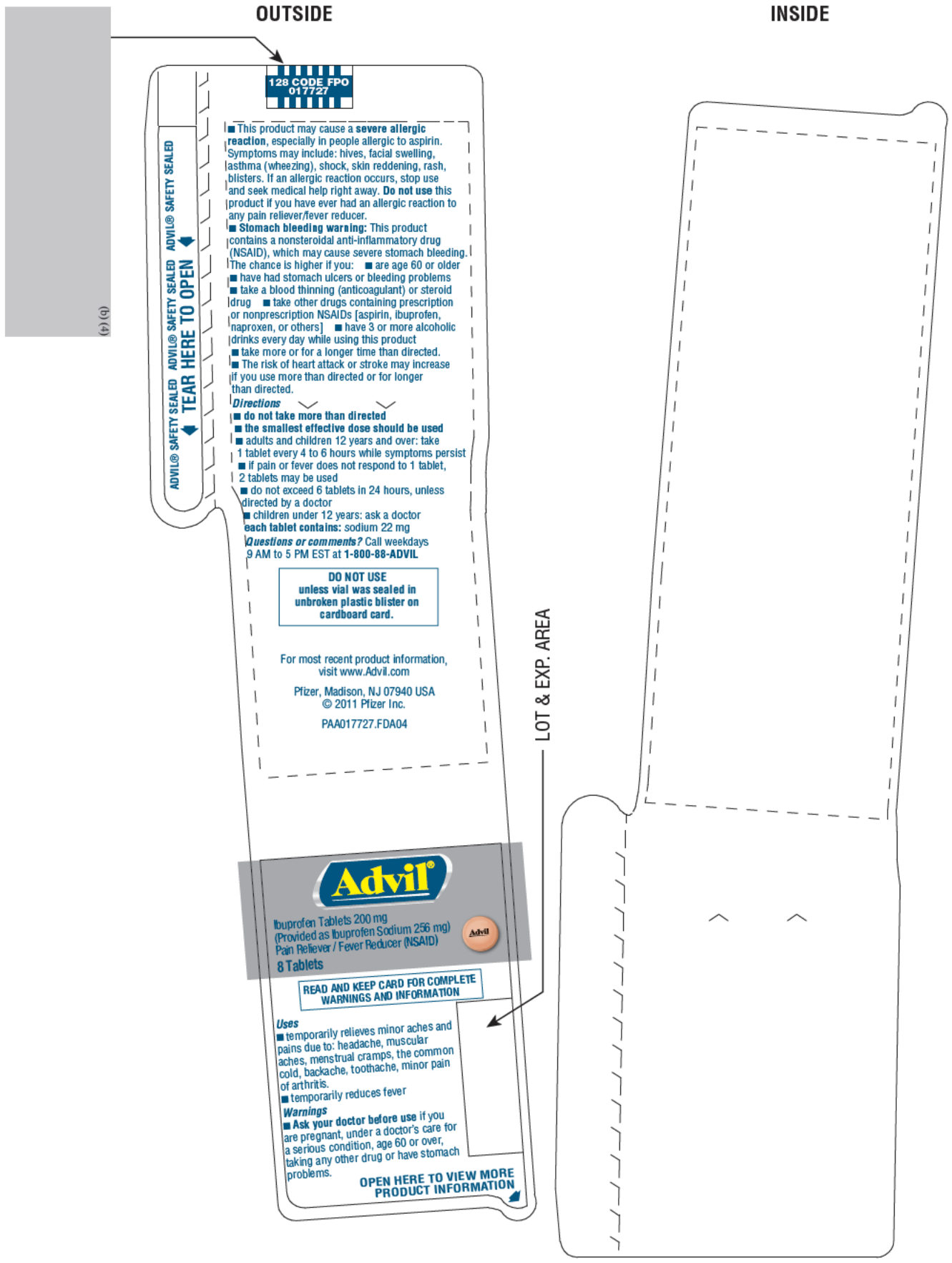
(1) _____ Date _____

DEPARTMENT	REVIEWED BY PRINT NAME	REVIEWED BY SIGNATURE	DATE	✔ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

(b) (4)

OUTSIDE

INSIDE



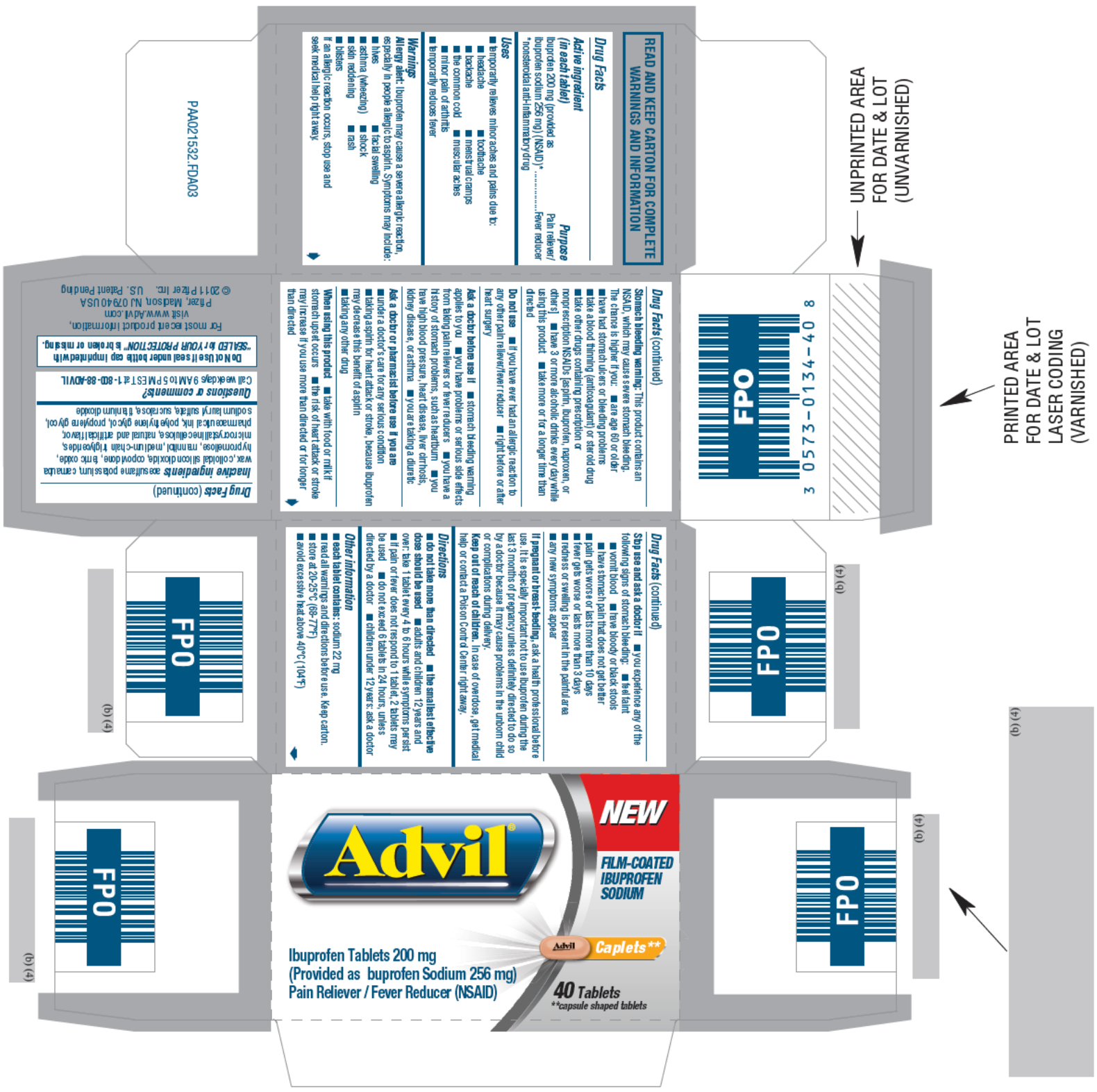
(b) (4)

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINES	.5 pt

REVIEWED BY			✓ with Changes
DEPARTMENT	PRINT NAME	SIGNATURE	DATE
Graphic Artist			
Labeling Compliance			
Packaging Engineer			
Medical			
Regulatory Affairs			
Marketing			
Legal			
Trademark			
Display Services			
Promotions			
Graphic Artist Closed			

RELEASED

Name _____ Date _____



DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	8 pt
• DRUG FACTS CONTINUED	7 pt
• HEADINGS	7 pt
• SUBHEADINGS/BODY TEXT	6 pt
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• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
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• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

DEPARTMENT	REVIEWED BY: PRINT NAME	SIGNATURE	DATE	✔ with Changes
Graphic Artist				☐
Labeling Compliance				☐
Packaging Engineer				☐
Medical				☐
Regulatory Affairs				☐
Marketing				☐
Legal				☐
Trademark				☐
Display Services				☐
Promotions				☐
Graphic Artist Closed				☐

(b) (4)

RELEASED

Name _____ Date _____

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

/s/

JOEL SCHIFFENBAUER
06/12/2012