

Wyeth Consumer Healthcare
Supplemental Application: Labeling - Additional
Tradename
December 30, 2003

NDA 21-441
Advil Allergy Sinus Caplets
Ibuprofen 200 mg / Pseudoephedrine HCl
30 mg / Chlorpheniramine Maleate 2 mg

150%

Advil® MULTI-SYMPTOM COLD 1 Tablet
IBUPROFEN 200 mg/PSEUDOEPHEDRINE HCl 30 mg/
CHLORPHENIRAMINE MALEATE 2 mg
ALLERGY, BLEEDING AND ALCOHOL WARNING.
READ CARTON BEFORE USE.
Wyeth Consumer Healthcare, Madison, NJ 07940
LOT
EXP
SEPARATE FIRST THEN PEEL & PUSH

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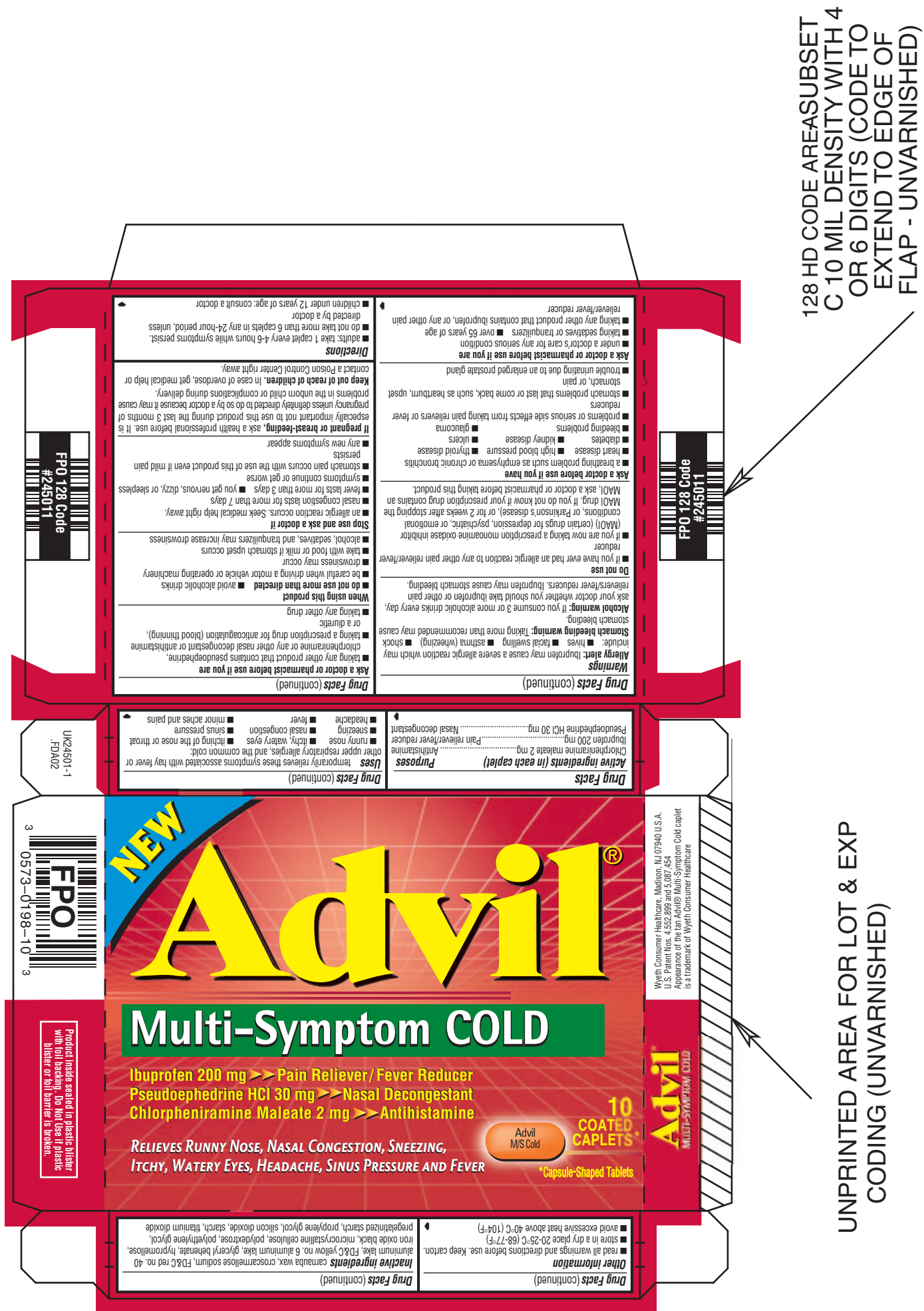
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SP1082-1.FDA01



128 HD CODE AREASUBSET
C 10 MIL DENSITY WITH 4
OR 6 DIGITS (CODE TO
EXTEND TO EDGE OF
FLAP - UNVARNISHED)

UNPRINTED AREA FOR LOT & EXP
CODING (UNVARNISHED)

Job Information	Color Legend
Date 3/31/04 PASS #4 Component # UK24501-1.FDA02 Drawing # 5181	
Identification	Printer Notes
Wyeth Consumer Healthcare Production Packaging Dept. Five / Farms Madison, NJ 07940 Phone: (973) 660-5595/5153 Fax: (973) 660-6048	PRINTER TO REPLACE FPO UPC'S WITH HI-RES DIGITAL ART ALSO PRINTER TO SUPPLY COLOR MATCHPRINT FOR COLOR APPROVAL PRIOR TO PRESS RUN. RUBINE RED INK PRINTS IN PLACE OF MAGENTA
Vendor Identification	
Production Packaging Dept. Cheng Lin SC Linda Hill 11/25/3	

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS Title	8 pt
• DRUG FACTS CONTINUED	7 pt
• HEADINGS	7 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	6.25 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE AFTER BULLETED SECTION	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

DEPARTMENT	REVIEWED BY		DATE	✓ with Changes
	Print Name	Signature		
Graphic Artist				<input type="checkbox"/>
Packaging Engineer				<input type="checkbox"/>
Labeling Compliance				<input type="checkbox"/>
Medical				<input type="checkbox"/>
Regulatory Affairs				<input type="checkbox"/>
Marketing				<input type="checkbox"/>
Legal				<input type="checkbox"/>
Trademark				<input type="checkbox"/>

RELEASED	
(1) _____	Date _____
(2) _____	Date _____

DIGITAL MECHANICAL
COLOR REPRESENTATION MAY BE OFF
FOLLOW COLOR LEGEND FOR ACTUAL COLOR.

Wyeth Consumer Healthcare
General Correspondence - Response to
Approvable Letter
April 30, 2004

NDA 21-441
Advil Allergy Sinus Caplets
Ibuprofen 200 mg / Pseudoephedrine HCl
30 mg / Chlorpheniramine Maleate 2 mg

ATTACHMENT 1

ADVIL[®] Multisymptom Cold Caplets

Ibuprofen 200 mg >> Pain reliever / Fever reducer
Pseudoephedrine HCl 30 mg >> Nasal Decongestant
Chlorpheniramine Maleate 2 mg >> Antihistamine

Active ingredients (in each caplet)

	Purposes
Chlorpheniramine maleate 2mg.....	Antihistamine
Ibuprofen 200 mg.....	Pain reliever/fever reducer
Pseudoephedrine HCl 30 mg.....	Nasal decongestant

Uses

temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:

- runny nose
- sneezing
- headache
- itchy, watery eyes
- nasal congestion
- minor aches and pains
- itching of the nose or throat
- sinus pressure
- fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning: Taking more than recommended may cause stomach bleeding.

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- heart disease
- kidney disease
- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or pain
- trouble urinating due to an enlarged prostate gland
- high blood pressure
- ulcers
- thyroid disease
- bleeding problems
- diabetes
- glaucoma

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking sedatives or tranquilizers
- over 65 years of age
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- taking any other product that contains pseudoephedrine, chlorpheniramine or any other nasal decongestant or antihistamine
- taking a prescription drug for anticoagulation (blood thinning), or a diuretic

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- taking any other drug
- taking aspirin for cardioprotection

When using this product

- **do not use more than directed**
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- drowsiness may occur
- take with food or milk if stomach upset occurs
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- nasal congestion lasts for more than 7 days
- fever lasts for more than 3 days
- you get nervous, dizzy, or sleepless
- symptoms continue or get worse
- stomach pain occurs with the use of this product even if mild pain persists
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use this product during the last 3 months of pregnancy unless definitely 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

- adults: take 1 caplet every 4-6 hours while symptoms persist.
- do not take more than 6 caplets in any 24-hour period, unless directed by a doctor
- children under 12 years of age: consult a doctor

Other information

- read all warnings and directions before use. Keep carton.
- store in a dry place 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

carnauba wax, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, glyceryl behenate, hypromellose, iron oxide black, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, silicon dioxide, starch, titanium dioxide