

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-076

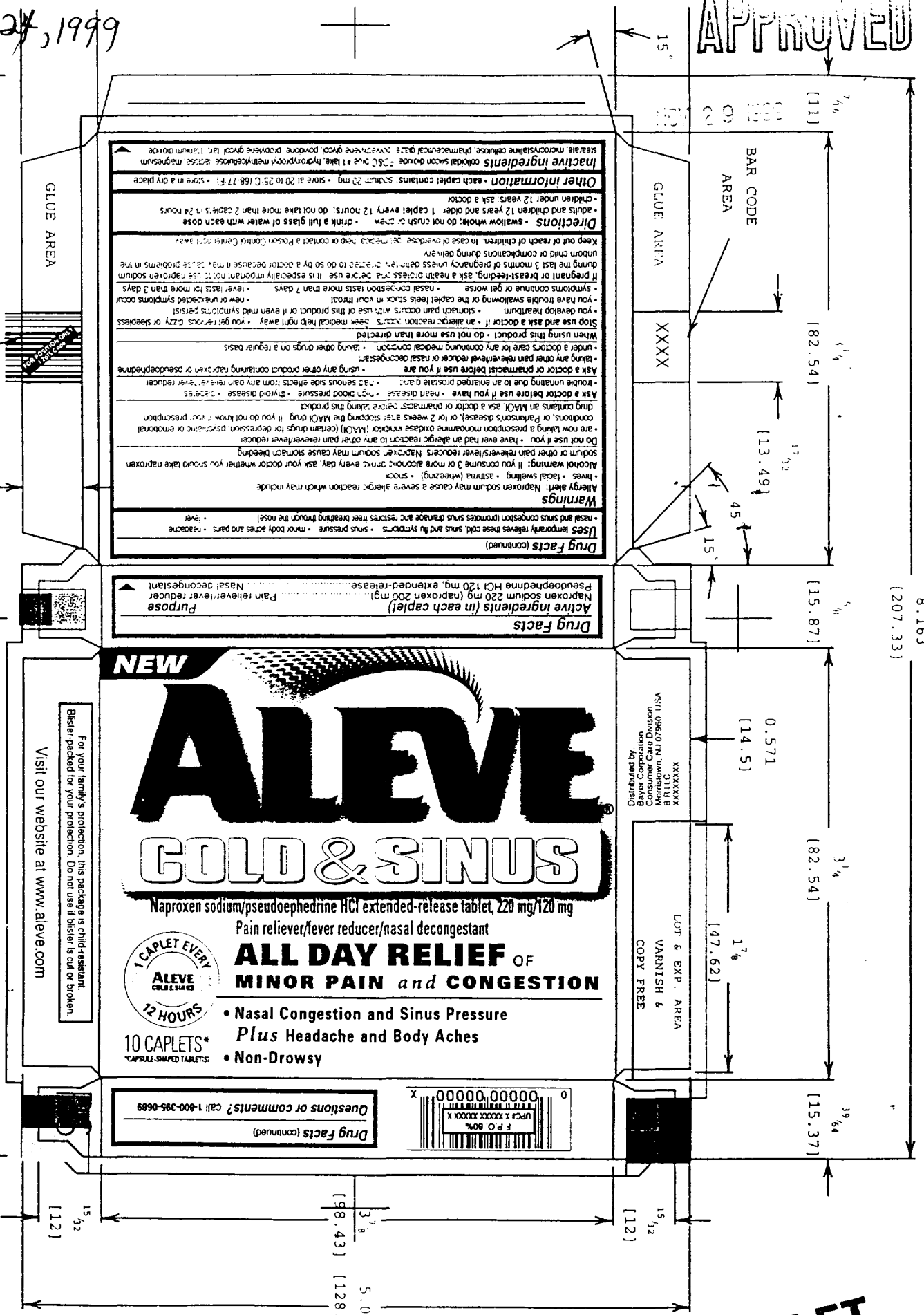
APPROVED DRAFT LABELING

Nov. 27, 1999

APPROVED

DRAFT

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[11.33]

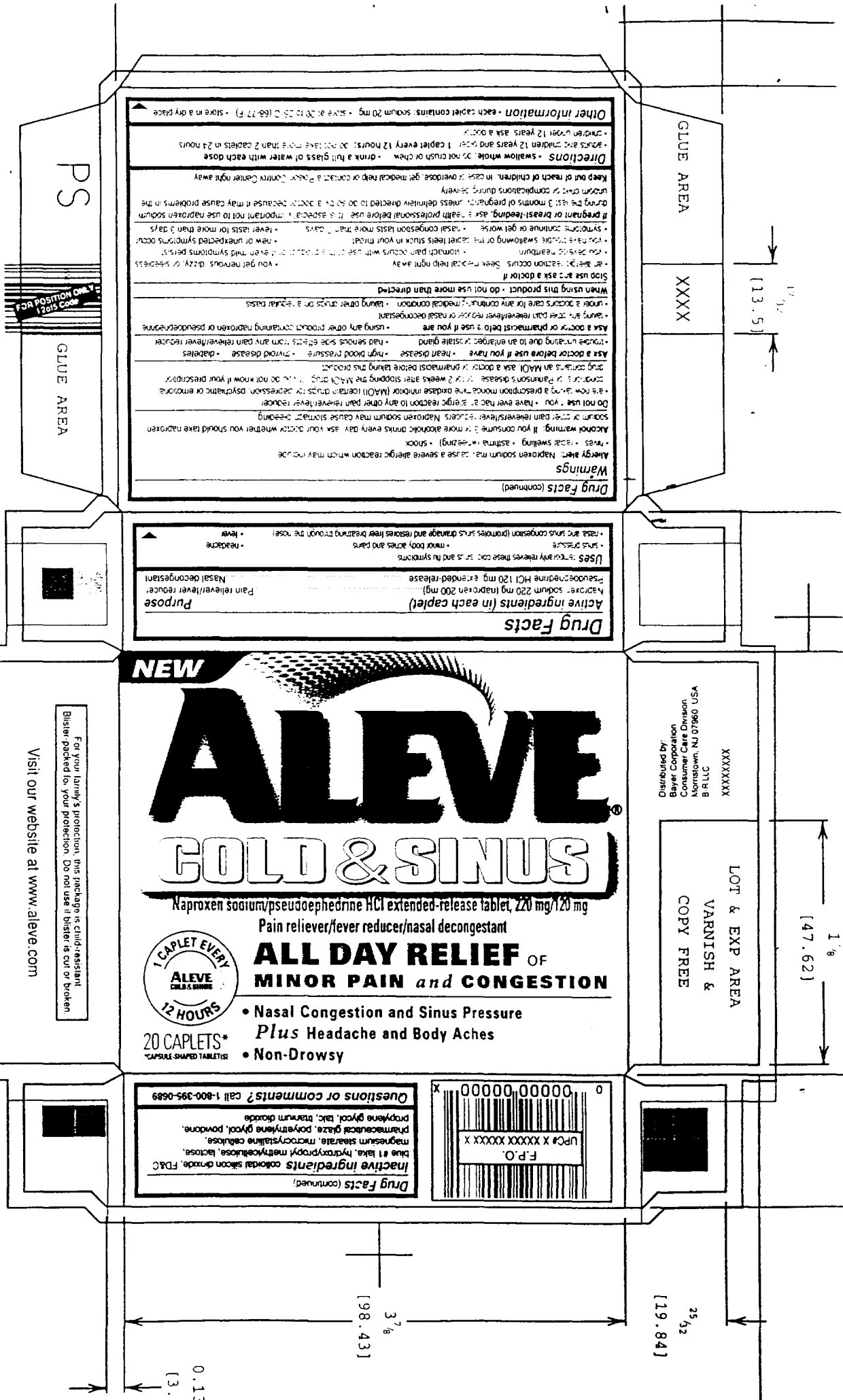


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Other information - each caplet contains: naproxen 220 mg - store at 20° to 25° C (68-77°F) - store in a dry place
 - children under 12 years - ask a doctor
 - adults and children 12 years and older - 1 caplet every 12 hours; do not take more than 2 caplets in 24 hours

Directions - swallow whole; do not crush or chew - drink a full glass of water with each dose

Warnings
 - allergic reaction occurs: Seek medical help right away
 - stomach pain occurs with use of this product and even mild symptoms persist
 - you get nervous, dizzy, or lightheaded
 - you have trouble swallowing or the caplet feels stuck in your throat
 - nasal congestion lasts more than 7 days
 - fever lasts for more than 3 days
 - new or unexpected symptoms occur

Drug Facts (continued)
Warnings
 - severe allergic reaction which may include hives, facial swelling, asthma (wheezing), or shock
 - alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain reliever/fever reducers. Naproxen sodium may cause stomach bleeding
 - do not use if you have ever had a serious allergic reaction to any other pain reliever/fever reducer
 - are now taking a prescription medicine (MAOI) or have taken MAOI (including St. John's Wort) for depression, psychiatric or emotional disorders, or Parkinson's disease in the last 2 weeks after stopping the MAOI drug, you do not know if you are taking a drug that contains an MAOI, ask a doctor or pharmacist before taking this product
 - ask a doctor before use if you have: heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to an enlarged prostate gland, had serious side effects from any pain reliever/fever reducer
 - using any other product containing naproxen or pseudoephedrine
 - taking other drugs on a regular basis
 - under a doctor's care for any condition, medical condition, or taking other drugs on a regular basis
 - when using this product - do not use more than directed
 - stop use and ask a doctor if:
 - an allergic reaction occurs
 - stomach pain occurs with use of this product and even mild symptoms persist
 - you have trouble swallowing or the caplet feels stuck in your throat
 - nasal congestion lasts more than 7 days
 - fever lasts for more than 3 days
 - new or unexpected symptoms occur
 - if pregnant or breastfeeding, ask a health professional before use. It is especially important not to use naproxen sodium 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

Drug Facts
Active ingredients (in each caplet)
 Naproxen sodium 220 mg (naproxen 200 mg)
 Pseudoephedrine HCl 120 mg extended-release
**Pain reliever/fever reducer
 Nasal decongestant**

Uses
 - temporarily relieves these cold, flu, and sinus symptoms:
 - sinus pressure
 - sinus pain
 - runny nose
 - sore throat
 - fever
 - headache
 - body aches and pains
 - minor body aches and pains
 - relieves fever
 - relieves pain
 - relieves sinus congestion (promotes sinus drainage and restores free breathing through the nose)

NEW

ALEVE

GOLD & SINUS

Naproxen sodium/pseudoephedrine HCl extended-release tablet, 220 mg/120 mg
 Pain reliever/fever reducer/nasal decongestant

1 CAPLET EVERY 12 HOURS

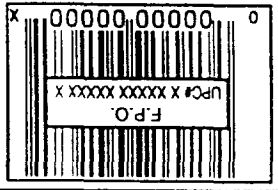
ALL DAY RELIEF OF MINOR PAIN and CONGESTION

- Nasal Congestion and Sinus Pressure
- Plus Headache and Body Aches
- Non-Drowsy

20 CAPLETS*
 CAPSULE-SHAPED TABLETS

Drug Facts (continued)
Inactive ingredients colloidal silicon dioxide, FDAC dye #1 lake, hydroxypropyl methylcellulose, lactose, pharmaceutical glaze, polyethylene glycol, povidone, polyethylene glycol, talc, titanium dioxide

Questions or comments? call 1-800-395-0689



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25/52
 (19.84)

1.8
 (47.62)

3.75
 (98.43)

0.13
 (3.5)

submitted Nov. 24, 1999

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GOLD & SINUS

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Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium 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

- swallow whole; do not crush or chew
- drink a full glass of water with each dose
- adults and children 12 years and older: 1 caplet every 12 hours; do not take more than 2 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- each caplet contains: sodium 20 mg
- store at 20-25° C (68-77°F)
- store in a dry place

Inactive ingredients colloidal silicon dioxide, FD&C blue #1 lake, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, polyethylene glycol, povidone, propylene glycol, talc, titanium dioxide

Questions or Comments? call 1-800-395-9629

Distributed by: Bayer Corporation
Consumer Care Division
Morrow, New Jersey 07960 USA

B-R LLC

Visit our website at www.aleve.com

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BACK

Illustrator 8.0

Drug Facts Header 14pt
Headings 8pt
Subheadings and body copy 6pt
Bullets 5pt
Leading 6.5

Rave Design REVISIONS BEGIN 5.10.99

1. Use FDA version of layout (front and back)
2. To active ingredients are: add "(extend release)"
ALT 7.28.99: Copy changes front & back
ALT 8.5.99: Copy changes front & back
ALT 11.18.99:
1. Change Drug facts copy
2. add copy to front panel
ALT 11.22.99: Change Drug facts copy
ALT 11.23.99: Change order of uses

B-330
DK.BLUE

Legend
tica, Formata,

submitted Nov. 24, 1999

3/8"

1/4"

1/4"

5.666"

1/4"

ALEVE[®]

GOLD & SINUS

Consumer labeling leaflet. Please save this for future use

Drug Facts

Active ingredients (in each caplet)	Purpose
Naproxen sodium 220 mg (naproxen 200 mg)	Pain reliever/fever reducer
Pseudoephedrine HCl 120 mg, extended-release	Nasal decongestant

Uses: temporarily relieves these cold, sinus and flu symptoms:

- sinus pressure • minor body aches and pains • headache
- nasal and sinus congestion (promotes sinus drainage and restores freer breathing through the nose)
- fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction which may include:

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

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

Do not use if you

- have ever had an allergic reaction to any other pain reliever/fever reducer
- 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

- heart disease • high blood pressure • thyroid disease • diabetes
- trouble urinating due to an enlarged prostate gland
- had serious side effects from any pain reliever/fever reducer

Ask a doctor or pharmacist before use if you are

- using any other product containing naproxen or pseudoephedrine
- taking any other pain reliever/fever reducer or nasal decongestant
- under a doctor's care for any continuing medical condition
- taking other drugs on a regular basis

When using this product • do not use more than directed

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you get nervous, dizzy, or sleepless
- you develop heartburn
- stomach pain occurs with use of this product or if even mild symptoms persist
- you have trouble swallowing or the caplet feels stuck in your throat
- new or unexpected symptoms occur
- symptoms continue or get worse
- nasal congestion lasts more than 7 days
- fever lasts for more than 3 days

FRONT

ALL COPY, LOGOS, BOX
AND RULES PRINTS B-330 BLUE

PRELIMINARY

A SCHAWK COMPANY

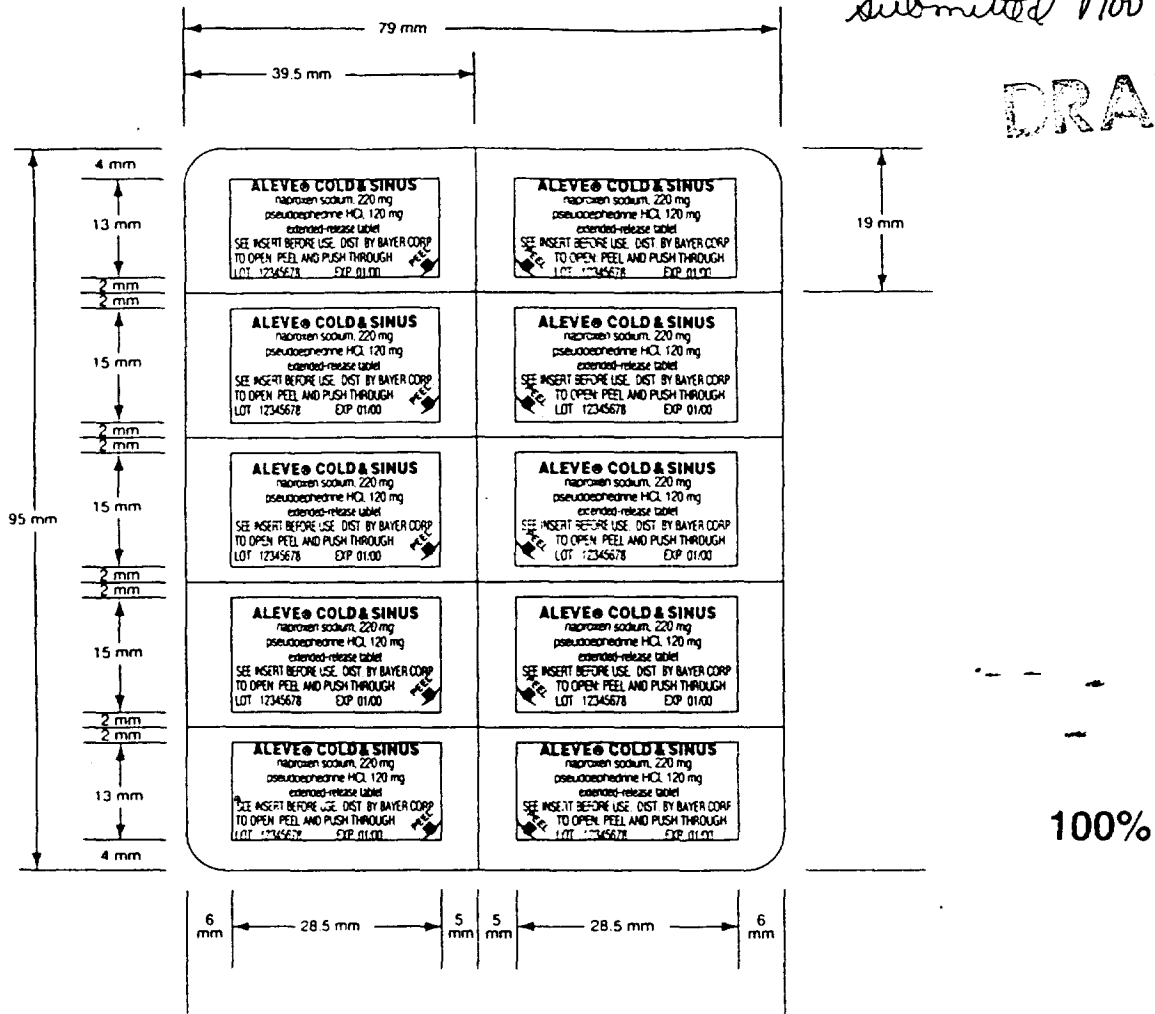
Rave Design

Date:	11.23.99	FIL:
Client:	Bayer Corporation	Pro:
Project:	Aleve Cold & Sinus 20s Insert XXXXXXXX	Lay
Project#:	7139	Fon
Job#:	995839	
UPC#:	(none)	

(1-800-621-1909)

submitted Nov. 24, 1999

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100%

Version 2

CHAWK COMPANY

Kave Design

Date: 11.18.99
 Client: Bayer Corporation
 Project: Aleve Caplets Blister Die (PLT-253)
 Project#:
 Job#: 997712
 UPC#: (none)

FILE INFORMATION

Program: Adobe Illustrator 8.0
 Layers: Die, Artwork, Background, Legend
 Fonts: (all Adobe) Helvetica, Formata, Univers