



*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

formerly Nonprescription Drug Manufacturers Association

November 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket Nos. 98N-0337, 96N-0420,
95N-0259, 90P-0201

Enclosed are the following documents presented by the Consumer Healthcare Products Association at the Public Workshop on the OTC Label Rule on November 23, 1999.

Attachment A, Framework for Feedback/Guidance/Amendment
Attachment B, Presentation for November 23, 1999 Public Workshop
Attachment C, Mockup Labels Illustrating Common Exemption Factors

These documents are submitted to the above dockets.

Sincerely,

R. William Soller, Ph.D.
Senior Vice President and Director,
Science & Technology
Consumer Healthcare Products Association

cc: Dr. Charles J. Ganley

98N-0337

TS1

Consumer Healthcare Products Association

Nov. 23, 1999 Feedback Meeting: Final Rule on OTC Label Content and Format

Framework for Feedback/Guidance/Amendment

- A. Use of Modified Format: the Modified Format may be used without the 60% calculation, as shown, for example, for outer containers with a front and back label (e.g., a bottle with no outer carton) and for boxes with small side panels that have limited available space for printing (e.g., a carton for a blister card).
- B. Voluntary directions and warnings, which are often important to the proper use of the product, may be included in the Drug Facts box when either complying with the Final Rule or requesting an exemption for formatting elements of the Final Rule.
- C. Exemption Process: As part of the exemption process, FDA will consider the size and number of Information Panels that are available for required labeling, the need for space to be used by the retail trade for pricing information, and the use of panels to limit the amount of package manipulation by the consumer, thus making for an easier-to-use and more consumer friendly label. The expectation is that in asking for exemptions companies will use a good faith effort to comply with the intent of the Final Rule.
1. Some or more aspects of the Final Rule may be considered in the exemption process.
 2. Exemptions requests maintaining a 6-point body text, for example, might include:
 - a. Omitting “**Drug Facts** (continued),” but placing arrows for purposes of directing attention to the next panel.
 - b. Placing the header, “Questions and Comments,” outside the Drug Facts box but on another area of the outer package label.
 - c. Decreasing type size of titles and headers down to 6-point type, with titles and headers nevertheless maintaining prominence through bold face type and/or color highlighting.
 - d. Omitting barlines and hairlines
 3. As part of exemptions that might include a reduction in type size of the body text below 6-points, the body text might be reduced to no less than 4.5 point type, consistent with dietary supplement, food, and cosmetic labeling regulations. In this regard, a consistent type size should be used for all body text ¹.
 4. Notification Process: A company may notify FDA that it intends to use any one or more of these types of common exemption requests and submit such notification to FDA with appropriate documentation to demonstrate the need for such an exemption(s). The agency has 14 days to object to the company’s notification, and provide reasons for its objection(s). If FDA does not provide written objections within 14 days of submission of receipt of a letter for exemption, then the exemption request may be considered approved.

¹ FDA indicated at the September 17, 1999 Feedback meeting the possibility that it might consider a selective reduction in type size for required information – e.g., actives, purposes, uses, warnings, and directions might be in 6-point type, while the remainder of the required text is in less than 6-point type. Since all required information is considered essential, there is no basis for distinguishing the relative importance of required information by type size. Hence, we advocate use of a proportional reduction of all body text, where needed.

Consumer Healthcare Products Association

Representing Producers of Quality Nonprescription Medicines and Dietary Supplements

Founded 1881

November 23, 1999 Feedback Meeting on OTC Label Content and Format: Feedback, Exemptions, and Special Packaging

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

William Bradley
Vice President, Technical Affairs

Revised: 11-22-99

Nov. 23, 1999

OTC Feedback Meeting

Attachment B

1

Overview

- Introduction
 - Feedback to Industry's Requests
 - Elements of the Final Rule Suitable for Exemption
 - Manufacturing Capabilities: ETL
 - Parity Across FDA-regulated Consumer Products
 - Modified vs. Standard Formats
- Exemption Process
 - Overview
 - Elements of a Feedback Letter
 - Examples of Typical Exemptions That Are Needed
 - Elements of a Feedback Letter: Notification Process
- Special Packaging

Introduction:

Feedback to Industry's Requests

- **CHPA's and CTFA's Requests**

- Use of columns (Draft Guidance dated 11/19/99; received 11/22/99)
- Light type on a dark background (trade dress)
- **2-year time extension**

It is vital that industry have timely and reasonable-feedback on these critical issues.

- **Feedback to Company Inquiries**

- Consistency is needed!

Introduction:

Elements of the Final Rule Suitable for Exemption

- From September 17th Feedback Meeting: Any one element, or a combination of elements, of the Final Rule may be suitable for exemption.
- The omission of one or more elements of the Final Rule is unlikely to be perceived by consumers as seriously affecting a “standard look,” particularly when those omissions may:
 - Help enhance the consumer friendliness of the label
 - Even help the appearance of a standard look (I.e., help to keep the labeling on 1-2 panels vs. 4 panels).

Introduction

Manufacturing Capabilities: ETL

- Types of “Extended Text Labeling” (ETL):
 - Spin Label
 - Accordion Label
 - Book Pages
 - Fold Down Fifth Panel
 - Bubble on a card
 - Fifth Panel

ETL is not an across-the-board easy answer to the problems posed by the Final Rule.

• Factors

- Reduced line speeds (thicker labels)
- Lack of data showing:
 - Consumer acceptance
 - Consumer understanding
 - Consumer friendliness
- Limited supplies
- Lack of experience with shipment (e.g. effect of heat/moisture on adhesive, type integrity etc.)
- Liability issues re: damage (removal) on the retail shelf
- Retailer acceptance of unwrapped ETL
- Reduction in label space (spin label)
- Non-standard appearance

Introduction: Parity Across FDA-Regulated Consumer Products

- FDA-regulated Consumer Products
 - OTC Drugs
 - Cosmetics
 - Foods, including dietary supplements
- Cosmetics, Foods and Dietary Supplements:
 - Columns
 - Trade Dress
 - 4.5-Point Type Size for Smaller Packages
- Why not parity for these elements of label formats across all FDA-regulated consumer products?

Introduction: Parity Across FDA-Regulated Consumer Products

- **Columns**

- A permitted format element for food nutrition labels
[21CFR 101.91(d),(e),(h),(j)]
- Permitted for dietary supplement labels *[21CFR 101.36(e)(11)]*

- **Light Type on Dark Background**

- Permitted for foods and dietary supplements *[21CFR 101.9(d)(1)(i); 101.36(e)(3)(ii)]*
- Cosmetic ingredient labeling needs only be “prominent and conspicuous” *[21CFR 701.3(b)]*

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size**

- 4.5-point type standard for smaller DS packages [21CFR 101.36(i)]
 - FDA relied on the CHPA Readability Guidelines as support for this rule [62Fed. Reg. 49838-9, Sept. 23, 1997]
- 4.5-point type is permitted on smaller food labels [21CFR 101.9(j)]
- < 6-point type is permitted on cosmetic ingredient labels [21CFR 701.3]

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size**
 - The argument that nutrition labeling or DS labeling is less significant to consumers than OTC labeling is unsupportable.
 - Safety issues are the same: food allergies can be fatal.
 - If 4.5-point type is permitted for food, DS, and cosmetic labeling, then FDA must permit 4.5-point type for OTC labeling.

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size: FDA review of CHPA information**
 - FDA set the 4.5-point type size for dietary supplements in reliance on the CHPA (then NDMA) voluntary label readability guidelines.
 - *“FDA set the minimum type size at 4.5 point in response to the majority of the comments, which stated that this minimum is consistent with the NDMA's Label Readability Guidelines used for over-the-counter drugs (Ref. 4). FDA has received information from NDMA that shows that it did not set this minimum arbitrarily or subjectively, but that it arrived at this minimum type size based on studies of visual acuity and demographics (Ref. 7). FDA has been persuaded by NDMA's data...” [62Fed. Reg. 49830-40, Sept. 23, 1997]*

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size: Evidence-base . . .**
 - The primary evidence that FDA cites does not support a 6-point minimum type size.
 - Watanabe study showed little difference in readability between 6.7- and 3.3-point type.
 - NCL study supported less than 6-point type.

Introduction: Parity Across FDA-Regulated Consumer Products

- **Type Size: Summary**
 - The 6-point minimum type size of the Final Rule conflicts with FDA regulations for food, dietary supplements and cosmetics.
 - The “support” cited for the 6-point type minimum in the Proposed and Final Rules is itself minimal at best.
 - Evidence supports 4.5-point type as readable.

Introduction:

Modified and Standard Formats

“20 1.66(d) (10) If the title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section, printed in accordance with the specifications in paragraphs (d)(1) through (d)(9) of this section, and any other FDA required information for drug products, and, as appropriate, cosmetic products, other than information required to appear on a principle display panel, requires more than 60 percent of the total surface area available to bear labeling, then the Drug Facts labeling shall be printed in accordance with the specifications set forth in paragraphs (d)(10)(i) through (d)(1 O)(v) of this section.”

- The Rule does not provide that the Standard Format is more readable than the Modified Format.
- The **60:40** calculation is therefore without foundation.
- The Modified Format should be able to be used without the **60:40** test.

Overview

- Introduction
 - Feedback to Industry's Requests
 - Elements of the Final Rule Suitable for Exemption
 - Manufacturing Capabilities: ETL
 - Consistency and Fairness Across FDA-regulated Consumer Products
 - Modified vs. Standard Formats
- Exemption Process
 - Overview
 - Elements of Feedback
 - Examples of Typical Exemptions That Are Needed
 - Elements of a Feedback Letter: Notification Process
- Special Packaging

Exemptions

Overview

- We seek feedback on the general concepts shown by the SKU's that CHPA submitted to FDA.
 - We are not seeking exemptions on the specific SKU's that we submitted on 11/2/99 to FDA.
 - We understand that there might be minor corrections needed to the label text in some cases, but these minor issues are not today's focus.
- We ask for feedback¹ on Modified Format, Voluntary Directions/Warnings and the types of general exemptions that might be considered by companies.

¹ For example: as a Feedback Letter, CPG, Guidance, etc.

See handout/attachment to overheads.

Exemptions

Elements of Feedback

- A Use of Modified Format without the 60:40 calculation
- B Voluntary directions and warnings may be included in the Drug Facts box when complying with the Final Rule or requesting an exemption for formatting elements of the Final Rule.
- C Feedback on Use of Common Exemptions
 - 1 Scope: one or combination of elements of the Final Rule may be considered for exemption.
 - 2 Exemption requests maintaining a 6-point body text
 - 3 Exemptions requests for a proportionate reduction in type size of the body text below 6-points but no less than 4.5-point type, consistent with food and cosmetic labeling regulations.

See handout/attachment to overheads.

Exemptions Label Mockups

Modified Format & Examples of Typical Exemptions

Modified Format: 50:50 Label & Thin Box

- Walgreen's Milk of Magnesia : Current 50:50 Label
- Walgreen's Milk of Magnesia : Standard Format on 50:50 label with run-off
- Walgreen's Milk of Magnesia: Modified Format fits on 50:50 label
- Triaminicin 12's Blister: Standard Format fits on 4 panels -- essentially a 50:50 label
- Triaminicin 12's Blister: Modified Format fits on 2 panels -- essentially a 50:50 label

Size-to-Fit

- Oxy 55's n t l a b e l
- Oxy 55's s t a n d a r d format with run-off
- Oxy 55's: Modified format with run-off
- Oxy 55's format with 5.7 body text fits
- Oxy 55's format with 5.7 body text fits

"Drug Facts (continued)" vs. Size-to-Fit

- Excedrin 24's Box: Current label
- Excedrin 24's Box: Modified Format with run-off
- Excedrin 24's Box: Modified Format (6-pt type) without "Drug Facts (continued)" fits
- Excedrin 24's Box: Modified Format and 5.5-pt type and "Drug Facts (continued)" fits

"Questions and Comments" outside of DF Box

- Contact 10's Blister: NDA approved label has "Questions and Comments" outside the Drug Facts box

Voluntary Directions.Warnings in Drug Facts Box

- Clear Away Pads: Current label with voluntary directions (diagram)
- Clear Away Pads: Standard format with voluntary directions (diagram)

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Use of Modified Format Without 60/40 Criterion**
 - 50/50 label (Mock-ups)
 - Milk of Magnesia bottle
 - Thin Carton (Mock-ups)
 - Triaminicin
 - Alka-Seltzer Plus Cold
 - **Rationale**
 - The 60/40 criterion is meaningless for packages having equal front and back labels (50/50) or for thin packages where the side panels are minimal.
 - The modified format provides a more standard look than the standard format, if it will fit on fewer panels.
 - The rule itself does not provide that the standard format is more readable than the modified format, so either should be allowed without a 60/40 numerical criterion.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Reduction in Type Sizes For Small Run-offs**
 - Proportionate Reduction in Type Sizes
 - Oxy Pads
 - Selective Reductions in Type Sizes
 - Nite Time (bottle)
 - Titles/headers to 6-point type, maintaining body text at 6-point and using highlighting (bold face/color) for titles/headers
 - **Rationale:**
 - For support of use of less than 6-point type (see previous overheads).
 - Use of a size-to-fit process
 - Note: proportionate reductions in type size of body text seem preferable to selective reductions, since there are no data to support that one part of essential (i.e., required) labeling is less important than another part of essential labeling.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Omission of “Drug Facts Continued”**
 - Examples:
 - Excedrin 24’s (not submitted on November 2nd)
 - Alka-Seltzer Plus Cold
 - Rationale:
 - Omission of “Drug Facts Continued” will not affect the “standard look,” as the consumer perceives the label, and may help the consumer friendly use of the label by maintaining all elements of the final rule.
 - Arrows, or similarly commonly understood routing icons, can be used to direct the consumer sequentially to different panels.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **“Questions and Comments,” Outside the Drug Facts Box**
 - Examples
 - Contact Capsules
 - Rationale:
 - FDA has approved NDA labeling with the new format, allowing “Questions and Comments” outside the Drug Facts Box.

Exemptions

Modified Format & Examples of Typical Exemptions.

- Use of Voluntary Directions and Warnings in the Drug Facts Box as part of the **60/40** calculation or other common exemptions
 - The Problem:
 - Situation: A company needs to incorporate voluntary directions (or warnings) into the Drug Facts Label.
 - Problem: FDA has indicated that the company may not use a Modified Format (vs. the Standard Format), since the Standard Format is a fit for the label if the voluntary information is not placed in the Drug Facts Box.
 - The Solution:
 - All calculations and common exemptions would be undertaken by the company assuming that voluntary directions and warnings are a part of the required information.
 - A exemption would be filed by the company.

Exemptions

Modified Format & Examples of Typical Exemptions.

- Use of Voluntary Directions and Warnings in the Drug Facts Box
 - Rationale:
 - We recognize that the “Drug Facts Box” is FDA’s imprimatur that the information within the Box is FDA approved.
 - Voluntary directions and warnings are not “FDA approved,” **but** they are essential to companies from the standpoint of providing adequate directions for specific dosage forms, for example, and for liability reasons.
 - Voluntary directions and warnings are most logically included within the Drug Facts Box, so that the label information is not disjointed.
 - By not allowing all calculations and common exemptions to be undertaken assuming that voluntary directions and warnings are a part of the required information, FDA will create an unfriendly label (e.g., illogical placement of warnings) and dampen company interest in providing useful information, thereby undermining OTC labeling.

Exemptions

Elements of Feedback

Notification Process

- ✓ Elements of Feedback
- ✓ Examples of Typical Exemption that Are Needed
- Notification Process for These Typical Exemptions:
 - A company may notify FDA that it intends to use any one or more of these types of common exemption requests and submit such notification to FDA with appropriate documentation to demonstrate the need for such an exemption(s). The agency has 14 days to object to the company's notification, and provide reasons for its objection(s). If FDA does not provide written objections within 14 days of submission of receipt of a letter for exemption, then the exemption request may be considered approved.

Special Packaging

- FDA needs to provide a flexible approach to small labels (e.g., convenience sizes and travel sizes; other small retail labels) because of the many package configurations.
- Without flexibility on this issue, companies will be faced with unacceptable decisions by FDA, given the what the agency is asking companies to do.

Special Packaging

- **For example, convenience and travel sizes account for 1-2 % of the market.**
 - This means that they are still a significant part of the OTC business . . . actually a core business for some companies.
 - This also means that any approach FDA would take in this area would affect a small number of packages relative to the very large number of packages for which the Final Rule is a fit.

Special Packaging

- **Special Packaging**
 - 1-2 dose convenience size
 - Short-term convenience
- **Types of Special Packaging**
 - Bubble on a hang card
 - Tin or plastic of 12's
 - Envelopes
 - Thin cartons
 - 2's foil
 - Rolls, single or blister packed
 - Small bottles
 - Others

Special Packaging

- **Types of approaches**
 - Type size exemption
 - Format exemption
 - Package insert in a tin/plastic, with outer statement directing consumers to read the package insert
 - Dispenser labeling
 - Other

Special Packaging

- **We need additional time on this issue.**
 - The solution to convenience sizes will have a retail trade and manufacture component, since one package type does not fit all class of trade.
 - Recommendation: Series of follow-up meetings with FDA.

Conclusion

- **Discussion**

- Feedback on use of columns and trade dress
- Common Exemptions
- Approach to special packaging
- Feedback on time extension



A 2-year time extension would allow us to develop mutually acceptable solutions to the problematic aspects of the Final Rule.



*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

Attachment C

This attachment to CHPA's November 23, 1999 presentation to FDA on the Final Rule on OTC label content and format contains OTC label mockups showing:

- The use of Modified Format on a 50:50 label (Walgreen's Milk of Magnesia) and on a thin carton (Triaminicin);
- A "size-to-fit" approach to small run-offs using less than 6-point type (Oxy 55's);
- Use of a Modified Format without use of "**Drug Facts** (continued)" and an alternative size-to-fit approach with "**Drug Facts** (continued)" and 5.5-point type (Excedrin 24's);
- Use of "Questions and Comments" outside the Drug Facts box on the label of an NDA-approved product (Contac);
- Use of voluntary directions in the Drug Facts box (Clear Away Pads).

The second page of this attachment is slide 17 of the oral presentation.

R. William Soller, Ph.D.
Senior Vice President
Director of Science & Technology
Consumer Healthcare Products Association

Exemptions Label Mockups

Examples of Typical Exemptions That Are Needed

Modified Format: 50:50 Label & Thin Box

- Walgreen's Milk of Magnesia : Current 50:50 Label
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- Triaminic 12's Blister: Standard Format fits on 4 panels -- essentially a 50:50 label
- Triaminic 12's Blister: Modified Format fits on 2 panels -- essentially a 50:50 label

Size-to-Fit

- Oxv 55's: Current label
- Oxv 55's: Standard format with run-off
- Oxv 55's: Modified format with run-off
- Oxv 55's format with 5.7 body text fits
- Oxv 55's format with 5.7 body text fits

"Drug Facts (continued)" vs. Size-to-Fit

- Excedrin 24's Box: Current label
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"Questions and Comments" outside of DF Box

- Contact 10's Blister: NDA approved label has "Questions and Comments" outside the Drug Facts box

Voluntary Directions, Warnings in Drug Facts Box

- Clear Away Pads: Current label with voluntary directions (diagram)
- Clear Away Pads: Standard format with voluntary directions (diagram)

LOGO GRADATION 100%-3% 341
BLOCK GRADATION 100%-3% 339

NDC 0363-0332-35

Walgreens
The Brand America Trusts

As Always Stimulant Free!

**milk of
magnesia**

laxative/antacid

- effective overnight relief
- very low sodium
- sugar free

✓ Compare to the active ingredient of Phillips®*



MINT

26 fl oz (1pt 10 oz) 769 mL

L 332 35 94 FA



SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

- Effective overnight relief of constipation
- Fast acting relief of acid indigestion

Directions: Shake well before using. Keep tightly closed and avoid freezing.
FOR LAXATIVE USE: Adults/Children-12 years and older: 2-4 tablespoonsful (TBSF) at bedtime or upon arising, followed by a full glass (8 oz.) of liquid.
Children: DO NOT USE DOSAGE CUP - 6-11 years: 1-2 tablespoonsful, followed by a full glass (8 oz.) of liquid.

2-5 years: 1-3 teaspoonsful, followed by a full glass (8 oz.) of liquid.
Under 2 years: Consult a doctor.

FOR ANTACID USE: DO NOT USE DOSAGE CUP - Adults/Children-12 years and older: 1-3 teaspoonsful with little water, up to four times a day or as directed by a doctor.

*This product is not manufactured or distributed by the Bayer Corporation, owner of the registered trademark Phillips®.

Distributed by: Walgreen Co.
Deerfield, IL 60015-4681

ITEM 503641



3 11917 02 16 6

ACTIVE INGREDIENT: Magnesium Hydroxide-400 mg per teaspoon (5 ml).

INACTIVE INGREDIENTS: Flavor, Mineral Oil, Purified Water, Saccharin Sodium.

INDICATIONS: AS A LAXATIVE-To relieve occasional constipation (irregularity). This product generally produces bowel movement in 1/2 to 6 hrs. AS AN ANTACID-To relieve acid indigestion, sour stomach, and heartburn.

Drug Interaction/Precaution: Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your doctor or other health professional.

LAXATIVE WARNINGS: Do not take any laxative if abdominal pain, nausea, vomiting, or kidney disease are present unless directed by a doctor. If you have noticed a sudden change in bowel habits persisting for over 2 weeks, consult a doctor before using a laxative. Laxative products should not be used for a period longer than 1 week unless directed by a doctor. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition.

Discontinue use and consult your doctor. ANTACID WARNINGS: Do not take more than the maximum recommended daily dosage in a 24 hour period (See Directions), or use the maximum dosage of this product for more than two weeks, or use this product if you have kidney disease, except under the advice and supervision of a doctor. May have laxative effect.

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Store at room temperature.

L 332 35 94 BA

FORMAT: STANDARD

TYPE SIZES:

TITLE: 10 pt Helvetica Bold Cond. Italic
 HEADINGS: 8 pt Helvetica Bold Cond. Italic
 SUBHEADINGS: 6 pt Helvetica Bold Cond.
 TEXT: 6 pt Helvetica Cond. Medium
 LEADING: 6.5 pt
 BULLETS: 5 pt Square with
 2 M'S spacing between statements
 TELEPHONE #: 6 pt Helvetica Bold Cond.
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

[DM]33235LBL1
 ELA 18M

NDC 0363-0332-35

Walgreens
 The Brand America Trusts

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

As Always Stimulant Free!



**milk
 magnesia**

laxative/antacid

- effective overnight relief
- very low sodium
- sugar free



Compare to the active ingredient of Phillips'®

MINT

26 fl oz (1pt 10 oz) 769 mL

33235 94 F1

Drug Facts

Active ingredient (in each 5 mL teaspoonful) Magnesium hydroxide 400mg. **Purpose** Saline Laxative/Antacid

Uses

- Laxative relieves
 - occasional constipation (irregularity)
 - generally produces bowel movement in 1/2 to 6 hours
- Antacid relieves
 - acid indigestion
 - sour stomach
 - heartburn

Warnings

Ask a doctor before use if you have

- kidney disease
- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product do not exceed the maximum recommended daily dosage in a 24-hour period

Stop use and ask a doctor if

- Laxative
 - you have rectal bleeding or no bowl movement after use. These could be signs of a serious illness
 - you need to use a laxative for more than one week
- Antacid
 - symptoms last for more than 2 weeks
 - product has a laxative effect

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 ■ shake well ■ drink a full glass (8oz) liquid with each dose

	Laxative	Antacid
adults and children 12 years and older	2-4 TBSP (30-60 mL) once a day	1-3 tsp (5-15 mL) up to 4 times a day
6 to under 12 years	1-2 TBSP (15-30 mL) once a day	ask a doctor
2 to under 6 years	1-3 tsp (5-15 mL) once a day	ask a doctor
under 2 years	ask a doctor	ask a doctor

Do not freeze. Store at room temperature lightly closed.

This product is not manufactured or distributed by The Bayer Corporation, owner of the registered trademark Phillips'®.

CODE AREA

33235 94 B1

Inactive ingredients flavor, mineral oil, purified water, sodium saccharin

Questions or comments? x-xxx-xxx-xxxx



Distributed by:
 Walgreen Co.
 Deerfield, IL 60015-4681

ITEM 503641

MODIFIED FORMAT

TYPE SIZES:

TITLE: 9 pt Helvetica Narrow Bold Italic
HEADINGS: 7 pt Helvetica Narrow Bold Italic
SUBHEADINGS: 6 pt Helvetica Narrow Bold
TEXT: 6 pt Helvetica Narrow
LEADING: 6 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Narrow Bold
HEAVY LINES: 1.5 PT
HAIRLINES: 0.5 PT

[DM]33235LBL1
 ELA 18M

NDC 0363-0332-35

Walgreens
 The Brand America Trusts

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION
 As Always **Stimulant Free!**



milk of magnesia

laxative/antacid

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Compare to the active ingredient of Phillips®*

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33235 94 F1

Drug Facts

Active ingredient (in each 5 mL teaspoonful) Magnesium hydroxide 400mg
Purpose Saline Laxative/Antacid

uses
 Laxative relieves occasional constipation (irregularity)
 Antacid relieves generally produces bowel movement in 1/2 to 6 hours
 acid indigestion, sour stomach, heartburn

Warnings
 Ask a doctor before use if you have kidney disease, stomach pain, nausea or vomiting
 a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product do not exceed the maximum recommended daily dosage in a 24-hour period.

Stop use and ask a doctor if you have rectal bleeding or no bowel movement after use. These could be signs of a serious illness. You need to use a laxative for more than one week.
 Antacid symptoms last for more than 2 weeks. product has a laxative effect.

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 . shakewell . drink a full glass (8oz) liquid with each dose

	Laxative	Antacid
adults and children 12 years and older	2-4 TBSP (30-60 mL) once a day	1-3 tsp (5-15 mL) up to 4 times a day
6 to under 12 years	1-2 TBSP (15-30 mL) once a day	ask a doctor
2 to under 6 years	1-3 tsp (5-15 mL) once a day	ask a doctor
under 2 years	ask a doctor	ask a doctor

Inactive ingredients flavor, mineral oil, purified water, sodium saccharin

Questions or comments? X-XXX-XXX-XXXX

Do not freeze. Store at room temperature, tightly closed.



ITEM 503641

*This product is not manufactured or distributed by The Bayer Corporation, owner of the registered trademark Phillips®.
 Distributed by:
 Walgreen Co.
 Deerfield, IL 60015-4681

CODE AREA

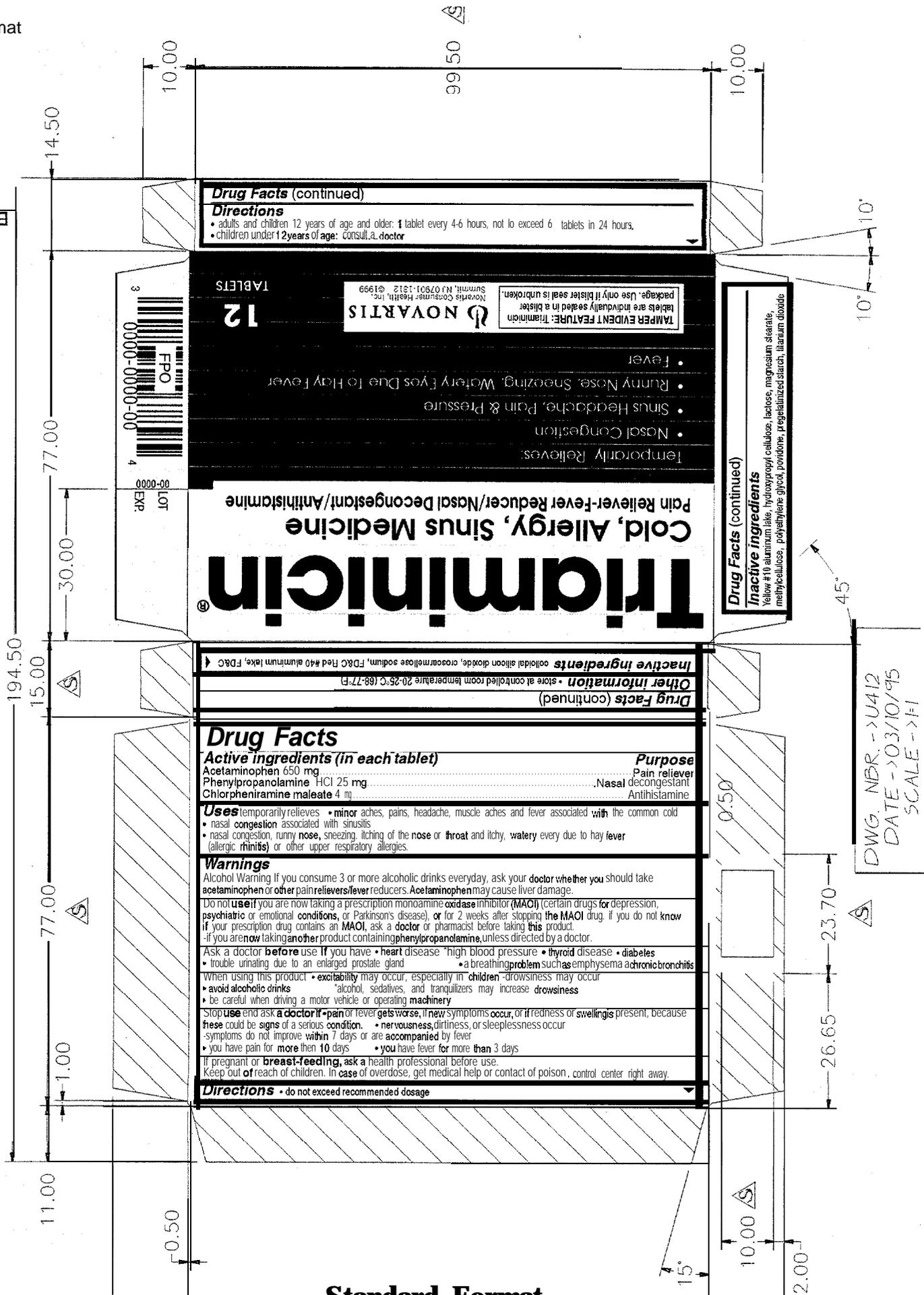
33235 94 B1

BOTTOM

FRONT

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BACK



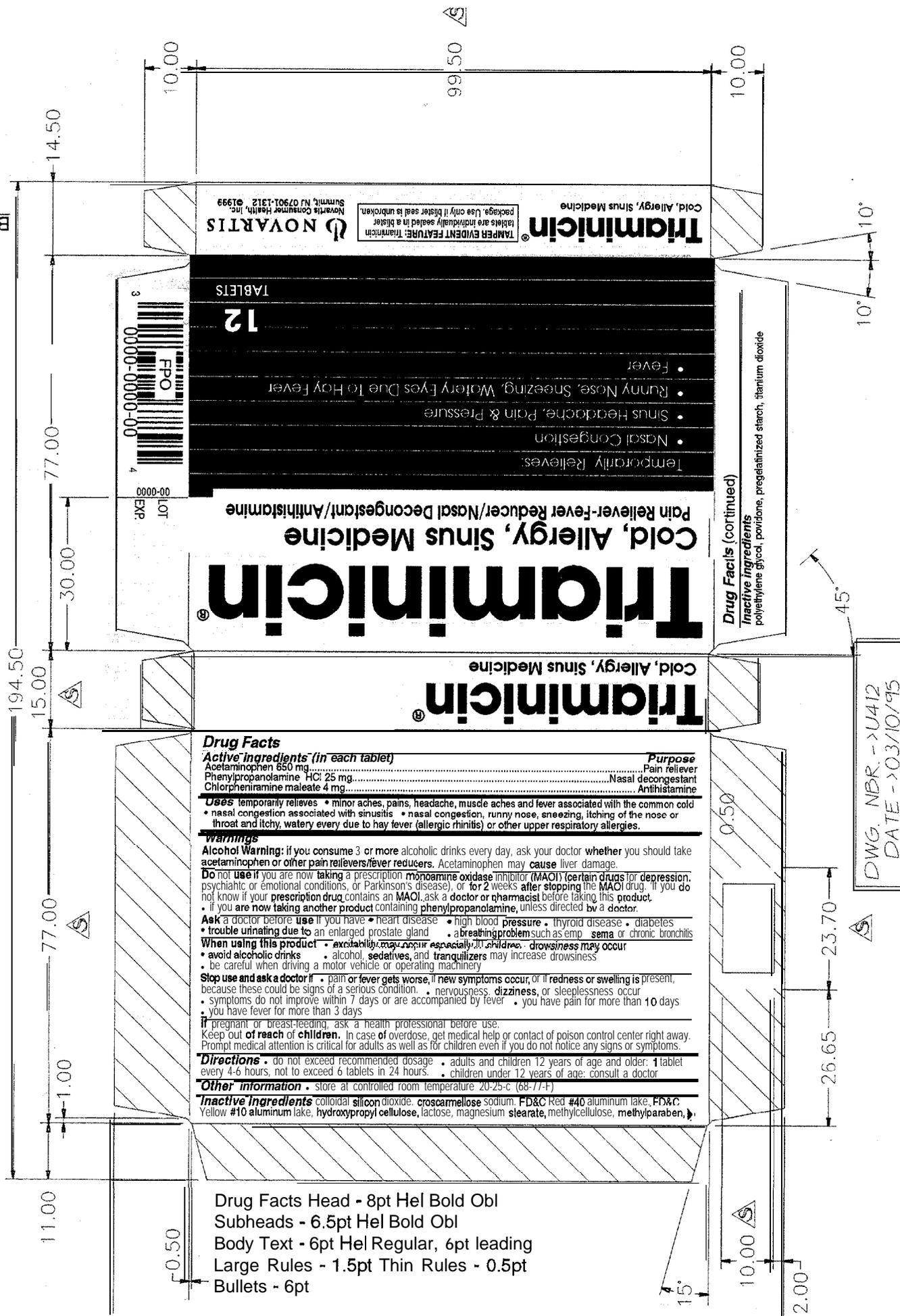
DWG. NBR. -> U412
 DATE -> 03/10/95
 SCALE -> 1:1

BOTTOM

FRONT

TOP

BACK



Triaminic®
Cold, Allergy, Sinus Medicine

TAMPER EVIDENT FEATURE: Triaminic® tablets are individually sealed in a blister package. Use only if blister seal is unbroken.

NOVARTIS
Novartis Consumer Health, Inc.
Summit, NJ 07901-1312 ©1999

12 TABLETS

Temporarily Relieves:

- Nasal Congestion
- Sinus Headache, Pain & Pressure
- Runny Nose, Sneezing, Watery Eyes Due To Hay Fever
- Fever

Triaminic®
Cold, Allergy, Sinus Medicine

Pain Reliever-Fever Reducer/Nasal Decongestant/Antihistamine

Drug Facts (continued)
Inactive ingredients
polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

Triaminic®
Cold, Allergy, Sinus Medicine

Drug Facts

Active ingredients (in each tablet)	Purpose
Acetaminophen 650 mg.....	Pain reliever
Phenylpropanolamine HCl 25 mg.....	Nasal decongestant
Chlorpheniramine maleate 4 mg.....	Antihistamine

Uses Temporarily relieves • minor aches, pains, headache, muscle aches and fever associated with the common cold • nasal congestion associated with sinusitis • nasal congestion, runny nose, sneezing, itching of the nose or throat and itchy, watery eyes due to hay fever (allergic rhinitis) or other upper respiratory allergies.

Warnings
Alcohol Warning: if you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.
Do not use 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.
• if you are now taking another product containing phenylpropanolamine, unless directed by a doctor.

Ask a doctor before use if you have • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • a breathing problem such as emphysema or chronic bronchitis

When using this product • excitability may occur especially in children • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if • pain or fever gets worse, if new symptoms occur, or if redness or swelling is present, because these could be signs of a serious condition. • nervousness, dizziness, or sleeplessness occur • symptoms do not improve within 7 days or are accompanied by fever • you have pain for more than 10 days • you have fever for more than 3 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 of poison control center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions • do not exceed recommended dosage • adults and children 12 years of age and older: 1 tablet every 4-6 hours, not to exceed 6 tablets in 24 hours. • children under 12 years of age: consult a doctor

Other information • store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, FD&C Red #40 aluminum lake, FD&C Yellow #10 aluminum lake, hydroxypropyl cellulose, lactose, magnesium stearate, methylcellulose, methylparaben, polyethylene glycol, povidone, pregelatinized starch, titanium dioxide

Drug Facts Head - 8pt Hel Bold Obl
Subheads - 6.5pt Hel Bold Obl
Body Text - 6pt Hel Regular, 6pt leading
Large Rules - 1.5pt Thin Rules - 0.5pt
Bullets - 6pt

DWG. NBR. ->U412
DATE ->03/10/95
SCALE ->1:1

Modified Format
Label does not meet the 60:40 criterion

Current Oxy Label

WARNINGS: For external use only. Do not leave pad on skin for an extended period of time. Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a physician. Keep away from eyes, lips and mouth. If contact occurs, flush thoroughly with water. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. If excessive drying of the skin or peeling occurs, reduce application to once a day or every other day. Store at room temperature. Avoid high temperatures (greater than 100 F). Protect from freezing. Keep away from flame, fire and heat. **KEEP TIGHTLY CLOSED.** For expiration date, see back of jar.

Distributed by:

SD SmithKline Beecham
SmithKline Beecham Consumer Healthcare, L.P.
Pittsburgh, PA 15290, Made in the U.S.A.

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5447XD



Questions? Call us at 1-800-245-1040
The Oxy Balance Skincare Guarantee. If for any reason you are not satisfied, please mail the remaining product, sales receipt, and reason for return for a full refund to: Oxy Balance Guarantee, SmithKline Beecham Consumer Healthcare, L.P., P.O. Box 1467, Pittsburgh, PA 15290
ACTIVE INGREDIENT: Salicylic Acid 2.0% w/v
OTHER: Citric acid, Fragrance, Glycerin, Menthol, Polyethylene Glycol, Propylene Glycol, Sodium Lauryl Sulfate, Water. Also contains Alcohol 50% v/v.



OXY Balance™ Maximum Deep Pore Cleansing Pads
Your skin condition changes daily with stress, moods, weather etc. which can lead to pimples. Oxy Balance provides your skin with the right balance of surface and deep pore cleansing. Oxy Balance Deep Pore Cleansing Pads thoroughly clean the skin's surface, while a maximum strength pharmaceutical ingredient penetrates pores to clean out trapped oil and dirt to help stop pimples before they start. The cool, fresh tingle means it's working. Only your skin knows what it needs to be cleaner and healthier.
INDICATION: For the prevention of acne.
DIRECTIONS: For young adults who regularly have pimples and oily skin and want clearer and healthier skin.
Cleanse the skin thoroughly before applying medication. Use a Cleansing Pad to cover the affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a physician. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

LOT NO. EXP.

Knock out area

Oxy Maximum Daily Cleansing Pads 55 count

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 times daily if needed or as directed by a doctor if bothersome dryness or peeling occurs, reduce application to once a day or every other day 		<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient Salicylic Acid 2.0%</td> <td>Purpose Acne Treatment</td> </tr> <tr> <td colspan="2">Uses treats and helps prevent acne pimples</td> </tr> <tr> <td colspan="2">Warnings For external use only</td> </tr> <tr> <td colspan="2">When using this product</td> </tr> </table> <ul style="list-style-type: none"> do not leave pad on skin using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a doctor. 	Active ingredient Salicylic Acid 2.0%	Purpose Acne Treatment	Uses treats and helps prevent acne pimples		Warnings For external use only		When using this product		<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> keep away from eyes, lips, and mouth. If contact occurs, flush thoroughly with water Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away
Active ingredient Salicylic Acid 2.0%		Purpose Acne Treatment									
Uses treats and helps prevent acne pimples											
Warnings For external use only											
When using this product											
<p>Other information</p> <ul style="list-style-type: none"> store at room temperature protect from freezing keep away from flame, fire and heat KEEP TIGHTLY CLOSED avoid high temperatures (greater than 100°F) 	<p>Directions</p> <ul style="list-style-type: none"> cleanse skin thoroughly before applying use a cleansing pad to cover the affected area with a thin layer 1 to 3 times daily 										
<p>Inactive ingredients alcohol (38.8% v/v), fragrance, isoceteth-20, polyol prepolymer-15, triethanolamine, bisodium EDTA, water</p>	<p>LOT NO. _____ EXP. _____</p>										

Questions call us at 1-800-897-6771

0 0000-0000-00 0 0000XX U.S. Patent #5,045,317 #4,917,800 #5,051,269

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CORNER

CORNER

CORNER

CORNER

CORNER

CORNER

Standard Format
 Helvetica 90% Condensed
 Drug Facts 8.5 pt.
 Headings 7 pt.
 Body Copy 6 pt.

Oxy Maximum Daily Cleansing Pads 55 count

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● protect from freezing ● keep away from flame, fire and heat ● KEEP TIGHTLY CLOSED ● avoid high temperatures (greater than 100°F) <p>Inactive ingredients alcohol (38.8% w/v), fragrance, isoceteih-20, polyolprepolymer-15, triethanolamine, trisodium EDTA, water</p> <p>Questions call us at 1-800-897-6771</p>	<p>NEW PATENTED FORMULA</p> <p>OXY BALANCE®</p> <p>maximum daily cleansing pads</p> <p>55 pads</p> <p>2% SALICYLIC ACID ACNE MEDICATION</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Salicylic Acid.....2.0%.....Acne.....Treatment</td> <td></td> </tr> </table> <p>Uses treats and helps prevent acne pimples</p> <p>Warnings For external use only</p> <p>When using this product</p> <ul style="list-style-type: none"> ● do not leave pad on skin ● using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a doctor. ● keep away from eyes, lips, and mouth. If contact occurs, flush thoroughly with water. 	Active ingredient	Purpose	Salicylic Acid.....2.0%.....Acne.....Treatment		<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ● cleanse skin thoroughly before applying ● use a cleansing pad to cover the affected area with a thin layer 1 to 3 times daily ● because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 times daily if needed or as directed by a doctor ● if bothersome dryness or peeling occurs, reduce application to once a day or every other day <p>Other information</p> <ul style="list-style-type: none"> ● store at room temperature
Active ingredient	Purpose						
Salicylic Acid.....2.0%.....Acne.....Treatment							
<p>Distributed by: SmithKline Beecham Consumer Healthcare, L.P. Pittsburgh, PA 15230 Made in the U.S.A. ©1999 SmithKline Beecham Oxy Balance and Logo Design and the various design elements of the packaging are registered trademarks of SmithKline Beecham.</p> <p>U.S. Patent #5,045,317 #4,917,800 #5,051,299</p>	<p style="text-align: center;">COR ER COR ER COR ER COR ER COR ER COR ER</p>	<p>LOT NO. EXP.</p>					

Modified Format
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 Drug Facts 8.5 pt.
 Headings 7 pt.
 Body Copy 6 pt.

Oxy Maximum Daily Cleansing Pads 55 count

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Drug Facts (continued)
Questions call us at 1-800-897-6771



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 0000XX
 U.S. Patent #5,046,317
 #1,917,800 #5,051,280

NEW PATENTED FORMULA

OXY

BALANCE®

SB **maximum**
 daily cleansing pads

55 pads 2% SALICYLIC ACID ACNE MEDICATION

Drug Facts	
Active ingredient Salicylic Acid 2.0%	Purpose Acne Treatment
Uses treats and helps prevent acne pimples	
Warnings For external use only	
When using this product	
<ul style="list-style-type: none"> do not leave pad on skin using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a doctor. Keep away from eyes, lips, and mouth. If contact occurs, flush thoroughly with water.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	

Drug Facts (continued)	
Directions	
● cleanse skin thoroughly before applying ● use a cleansing pad to cover the affected area with a thin layer 1 to 3 times daily ● because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 times daily if needed or as directed by a doctor ● if bothersome dryness or peeling occurs, reduce application to once a day or every other day	
Other information	
● store at room temperature ● protect from freezing ● keep away from flame, fire and heat ● KEEP TIGHTLY CLOSED ● avoid high temperatures (greater than 100°F)	
inactive ingredients alcohol (38.8% v/v), fragrance, isocetoth-20, polypropylene-15, triethanolamine, trisodium EDTA, water	
LOT NO.	EXP.

LABEL OVERLAPS TO COVER

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Modified Format
 Helvetica 85% Condensed
 Drug Facts 7 pt.
 Headings 6.8 pt.
 Body Copy 5.7 pt.

Oxy Maximum Daily Cleansing Pads 55 count

Drug Facts (continued)

Inactive ingredients alcohol (38.8% v/v), fragrance, isoceteth-20, polyolpropolymer-15, triethanolamine, trisodium EDTA, water

Questions call us at 1-800-897-6771

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U.S. Patent #5,045,317
 #4,917,800 #5,051,290

NEW PATENTED FORMULA

OXY

BALANCE®

SD **maximum**
daily cleansing pads

55 pads 2% SALICYLIC ACID ACNE MEDICATION

Drug Facts

Active ingredient	Purpose
Salicylic Acid 2.0%	Acne Treatment

Uses treats and helps prevent acne pimples

Warnings
 For external use only
 When using this product

- do not leave pad on skin
- using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a doctor.
- keep away from eyes, lips, and mouth. If contact occurs, flush thoroughly with water.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- cleanse skin thoroughly before applying
- use a cleansing pad to cover the affected area with a thin layer 1 to 3 times daily
- because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day

Other information

- store at room temperature
- keep away from flame, fire and heat
- avoid high temperatures (greater than 100°F)
- protect from freezing
- KEEP TIGHTLY CLOSED

LOT NO. EXP.

LABEL OVERLAPS TO COVER

CORNER

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CORNER

Standard Format
 Helvetica 85% Condensed
 Drug Facts 7 pt.
 Headings 6.8 pt.
 Body Copy 5.7 pt.

Date: October 25, 1999 File Name: 7/6_24.Parent Modified Format/ver.1

Drug Fact Headers – 8.0 pts

(Helvetica Neu Condensed Sold Oblique – 88% Horizontally Scaled)

Headers – 7pts

(Helvetica Neu Condensed Sold Oblique – 88% Horizontally Scaled)

Body Copy – 6/6pts

(Helvetica Neu Condensed Light – 88% Horizontally Scaled)

PS

Drug Facts (continued)

Alcohol warning: You consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen and aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.

Do not use • If you have ever had an allergic reaction to any other pain relievers/fever reducers

Ask a doctor before use if you have • asthma • liver disease • kidney disease • bleeding problems • ulcers • stomach problems such as heartburn, upset stomach, or stomach pain that do not go away or recur

Ask a doctor or pharmacist before use if you are • allergic to aspirin • taking a prescription drug for • anticoagulation (blood thinning) • diabetes • gout • arthritis

Stop use and ask a doctor if • an allergic reaction occurs. Seek medical help right away

- fever gets worse or lasts for more than 3 days
- new symptoms occur
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin 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. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions drink a full glass of water with each dose

- adults and children 12 years and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours
- children under 12 years: ask a doctor.

Other information • store at room temperature

Inactive ingredients benzoic acid, hydroxypropylcellulose, hydroxypropyl methylcellulose, microcrystalline cellulose, mineral oil, polyorbate 20, povidone, propylene

Drug Facts (continued)

glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, may also contain: camauba wax, FD&C blue #1, titanium dioxide

Questions or comments? 1-800-468-7746

Excedrin
Acetaminophen, Aspirin and Caffeine

EXTRA STRENGTH

24 COATED TABLETS

E.P.O.

Drug Facts

Active Ingredients (in each tablet)	Purposes
Acetaminophen 2.50 mg	Pain reliever
Aspirin 250 mg	Pain reliever
Caffeine 65 mg	Pain reliever aid

Uses for the temporary relief of minor aches and pains associated with

- headache
- a cold
- muscular aches
- arthritis
- toothache
- sinusitis
- premenstrual & menstrual cramps

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox, or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

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

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

24 COATED TABLETS

EXTRA STRENGTH

Excedrin

PAIN RELIEVER

DENTS, BRISTOL MYERS SQUIBB COMPANY
PARKE, DAVIS & COMPANY, DIVISION OF
SQUIBB LABORATORIES, KENILWORTH, NJ 07033
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CAUTION: ASPIRIN MAY CAUSE GASTRIC ULCERS AND BLEEDING. ASPIRIN MAY CAUSE ALLERGIC REACTIONS. ASPIRIN MAY CAUSE REYE'S SYNDROME. ASPIRIN MAY CAUSE HEARING LOSS. ASPIRIN MAY CAUSE RINGING IN THE EARS. ASPIRIN MAY CAUSE LOSS OF HEARING. ASPIRIN MAY CAUSE STOMACH PAIN. ASPIRIN MAY CAUSE STOMACH BLEEDING. ASPIRIN MAY CAUSE LIVER DAMAGE. ASPIRIN MAY CAUSE STOMACH BLEEDING.

Date: October 25, 1999 File Name: 9/29_24.Parent Modified/Ver.2e

Drug Fact Headers – 8.0 pts

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Headers – 7 pts

(Helvetica Neu Condensed Bold Oblique – 88% Horizontally Scaled)

Body Copy – 6/6 pts

(Helvetica Neu Condensed Light – 88% Horizontally Scaled)

PS

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen and aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.

Do not use • if you have ever had an allergic reaction to any other pain relievers/fever reducers

Ask a doctor before use if you have • asthma • liver disease • kidney disease • bleeding problems • ulcers • stomach problems such as heartburn, upset stomach, or stomach pain that do not go away or recur

Ask a doctor or pharmacist before use if you are • allergic to aspirin • taking a prescription drug for: • anticoagulation (thinning of the blood) • diabetes • gout • arthritis

Stop use and ask a doctor if • an allergic reaction occurs. Seek medical help right away

- fever gets worse or lasts for more than 3 days
- new symptoms occur
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use.
It is especially important not to use aspirin 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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions drink a full glass of water with each dose

- adults and children 12 years and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours
- children under 12 years: ask a doctor.

Other information • store at room temperature

Inactive ingredients benzocaine, hydroxypropylcellulose, hydroxypropyl methylcellulose, microcrystalline cellulose, mineral oil, polysorbate 20, povidone, propylene glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, may also contain: camauaba wax, FD&C blue #1, titanium dioxide

Questions or comments? 1-800-468-7746

24's



Pain Reliever

Excedrin®

Acetaminophen, Aspirin and Caffeine

EXTRA STRENGTH

24 COATED TABLETS

Pain Reliever

Excedrin™

Acetaminophen, Aspirin and Caffeine

EXTRA STRENGTH

24 COATED TABLETS

DETR, INC. BOSTON-ANDERS SQUARE CO.
NY, NY 10154 ©1999 MADE IN USA

TEMPERATURE SENSITIVE SEAL
IMPROVED SEALING SYSTEM
BOTTLE CAP AND NECK IS BROKEN OR MISSING

CAUTION: MADE FROM 100% RECYCLED PAPERBOARD
PRINTED AND MANUFACTURED IN THE U.S.A.

000000000 000000-05-00

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 250 mg
Aspirin 250 mg
Caffeine 65 mg

Purposes

Pain reliever
Pain reliever
Pain reliever aid

Uses for the temporary relief of minor aches and pains associated with

- headache
- a cold
- muscular aches
- toothache
- sinusitis
- premenstrual & menstrual cramps
- arthritis

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox, or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

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

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

Date: July 6, 1999 File Name: 7/6_24.Parent Modified Format/ver.3

Drug Fact Headers – 7.5 pts

(Helvetica Neu Condensed Bold Oblique – 88% Horizontally Scaled)

Headers – 6.5pts

(Helvetica Neu Condensed Bold Oblique -88% Horizontally Scaled)

Body Copy – 5.5/5.5pts

(Helvetica Neu Condensed Light – 88% Horizontally Scaled)



Drug Facts (continued)

you should take acetaminophen and aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.

Do not use • if you have ever had an allergic reaction to any other pain relievers/fever reducers.

Ask a doctor before use if you have • asthma • liver disease • renal disease
 • bleeding problems • ulcers • stomach problems such as heartburn, upset stomach, or stomach pain that do not go away or recur

Ask a doctor or pharmacist before use if you are • allergic to aspirin • taking a prescription drug for: • anticoagulation (thinning of the blood) • diabetes • gut • arthritis

Stop use and ask a doctor if • an allergic reaction occurs. Seek medical help right away
 • fever gets worse or lasts for more than 3 days • new symptoms occur
 • pain gets worse or lasts for more than 10 days • redness or swelling is present
 • ringing in the ears or loss of hearing occurs

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

Drug Facts (continued)

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions drink a full glass of water with each dose
 • adults and children 12 years and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours • children under 12 years: ask a doctor.

Other Information • store at room temperature

Inactive Ingredients benzoic acid, hydroxypropylcellulose, hydroxypropylmethylcellulose, microcrystalline cellulose, mineral oil, polysorbate 20, povidone, propylene glycol, simethicone emulsion, sodium monolaurate, stearic acid, may also contain: carnauba wax, FD&C blue #1, titanium dioxide

Questions or comments? 1-800-488-7746

Drug Facts

Active Ingredients (in each tablet)

Acetaminophen 250 mg	Purposes
Aspirin 250 mg	Pain reliever
Caffeine 65 mg	Pain reliever
	Pain reliever aid

Uses for the temporary relief of minor aches and pains associated with

• headache	• a cold	• muscular aches	• arthritis
• toothache	• sinusitis	• premenstrual & menstrual cramps	

Warnings
Reye's syndrome: Children and teenagers should not use this drug for chicken pox, or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.
Alergy alert: aspirin may cause a severe allergic reaction which may include:
 • hives • angioedema • asthma/wheezing • shock
Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether

Pain Reliever

Excedrin®

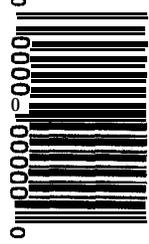
Acetaminophen, Aspirin and Caffeine



EXTRA STRENGTH

24 COATED TABLETS

EXP



Pain Reliever

Excedrin

Acetaminophen, Aspirin and Caffeine

EXTRA STRENGTH

24 COATED TABLETS

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 NY, NY 10154 ©1999 MADE IN USA

TEMPERATURE SENSITIVE: DO NOT USE IF SEAL IMPRINTED WITH "BASTOL-AYERS" AND NO BOTTLE CAP AND NECK IS BROKEN OR MISSING.

CONTAINS ASPIRIN. MAY CAUSE ALLERGIC REACTIONS.
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Pain Reliever

Excedrin

Acetaminophen, Aspirin and Caffeine

EXTRA STRENGTH

24 COATED TABLETS

DISTR. BY: BASTOL-AYERS SOURCE CO.
 NY, NY 10154 ©1999 MADE IN USA

TEMPERATURE SENSITIVE: DO NOT USE IF SEAL IMPRINTED WITH "BASTOL-AYERS" AND NO BOTTLE CAP AND NECK IS BROKEN OR MISSING.

CONTAINS ASPIRIN. MAY CAUSE ALLERGIC REACTIONS.
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IDM

Imaging & Design Management

10 capsules
A3.8.13.99 km

TIMED RELEASE

10 CAPSULES

CONTAC

CONTAC®

12 HOUR COLD CAPSULES

Chlorpheniramine maleate and phenylpropranolamine HCl

ANTIHISTAMINE/NASAL DECONGESTANT

12 HOUR RELIEF OF:

NASAL & SINUS CONGESTION
RUNNY NOSE & SNEEZING
ITCHY, WATERY EYES

NEW & IMPROVED!

Smaller Capsule
For Easier Swallowing

10 CAPSULES

Lot:
Exp:

do not use if foil is broken. Each Contac capsule is protected by a red Perma-Seal® band which bonds the two capsule halves together. do not use if capsule or band is broken. This carton is protected by a clear overwrap printed with "safety-seal"; do not use if overwrap is missing or broken.

Retain outer carton for complete directions and warnings. Comments or Questions? Call 1-800-245-1040 weekdays

Distributed by:
SmithKline Beecham Consumer Healthcare, L.P.
Pittsburgh, PA 15230. Made in the U.K.
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2271581

Drug Facts

Active ingredients (in each extended release capsule)	Purpose
Chlorpheniramine maleate USP 8 mg.....	Antihistamine
Phenylpropranolamine HCl USP 75 mg...	Nasal decongestant

Uses ■ temporarily relieves these symptoms of the common cold, hay fever or other upper respiratory allergies

- nasal congestion
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose/throat

■ temporarily relieves nasal congestion associated with sinusitis

Warnings

Do not use if you are now taking

- another product containing phenylpropranolamine
- 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

- high blood pressure
- heart disease
- glaucoma
- thyroid disease
- diabetes
- a breathing problem such as emphysema or chronic bronchitis
- difficulty urinating due to enlargement of the prostate gland

Ask your doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- do not use more than directed
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic drinks

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or occur with a fever

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: one capsule every 12 hours; not more than 2 capsules in 24 hours unless directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- store in a dry place
- store at 20°-25°C (68°-77°F)

Inactive ingredients aluminum hydrate, ammonium hydroxide, black iron oxide, carmine, deionized water, ethylcellulose, fractionated coconut oil, gelatin, hydroxypropyl methylcellulose, lecithin, oleic acid, polyethylene glycol, polysorbate 80, polyvinyl alcohol, red iron oxide, shellac, soya lecithin, starch, sucrose, synthetic yellow iron oxide, talc, titanium dioxide, xanthan gum



CONTAC

Each Contac capsule contains "Troy Time Pills"® over 700 medicine beads. Some go to work right away. The rest are scientifically timed to dissolve slowly to give up to 12 hours of relief.

10 CAPSULES

12 HOUR COLD CAPSULES

60% More
Applications
Than The Leading
One Step Plantar
Competitor

DrScholl's®

UPC 36054

**Clear Away®
One Step
Plantar**
Salicylic Acid
Wart Remover
For Feet

Easy one step
application for fast
removal and pain relief

16 Medicated
Cushioning Pads

S-98-61

DrScholl's®

Clear Away®
One Step Plantar



WART REMOVER SYSTEM FOR FEET

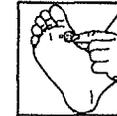
• Cushions as it heals™ • Clinically proven ingredient • Odorless

INDICATIONS:

For removal of plantar warts on the bottom of the foot. The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern.

DIRECTIONS:

Wash and dry affected area thoroughly. Apply medicated cushioning pad, positioning medicated disc directly over plantar wart. Repeat procedure every 48 hours (until wart is removed) for up to 12 weeks.



NOTE:

When applying medicated cushioning pad to wart, secure adhesive firmly to skin.

WARNING:

For external use only. Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation. If discomfort persists, see your doctor. Do not use on moles, birthmarks, warts with hair growing from them, genital warts or warts on the face or mucous membranes. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

ACTIVE INGREDIENT:

Medicated discs contain Salicylic Acid 40% in a rubber-based vehicle.

This package contains:

16 medicated cushioning pads.

Store between 15° and
30°C (59° and 86°F).

www.drscoll's.com

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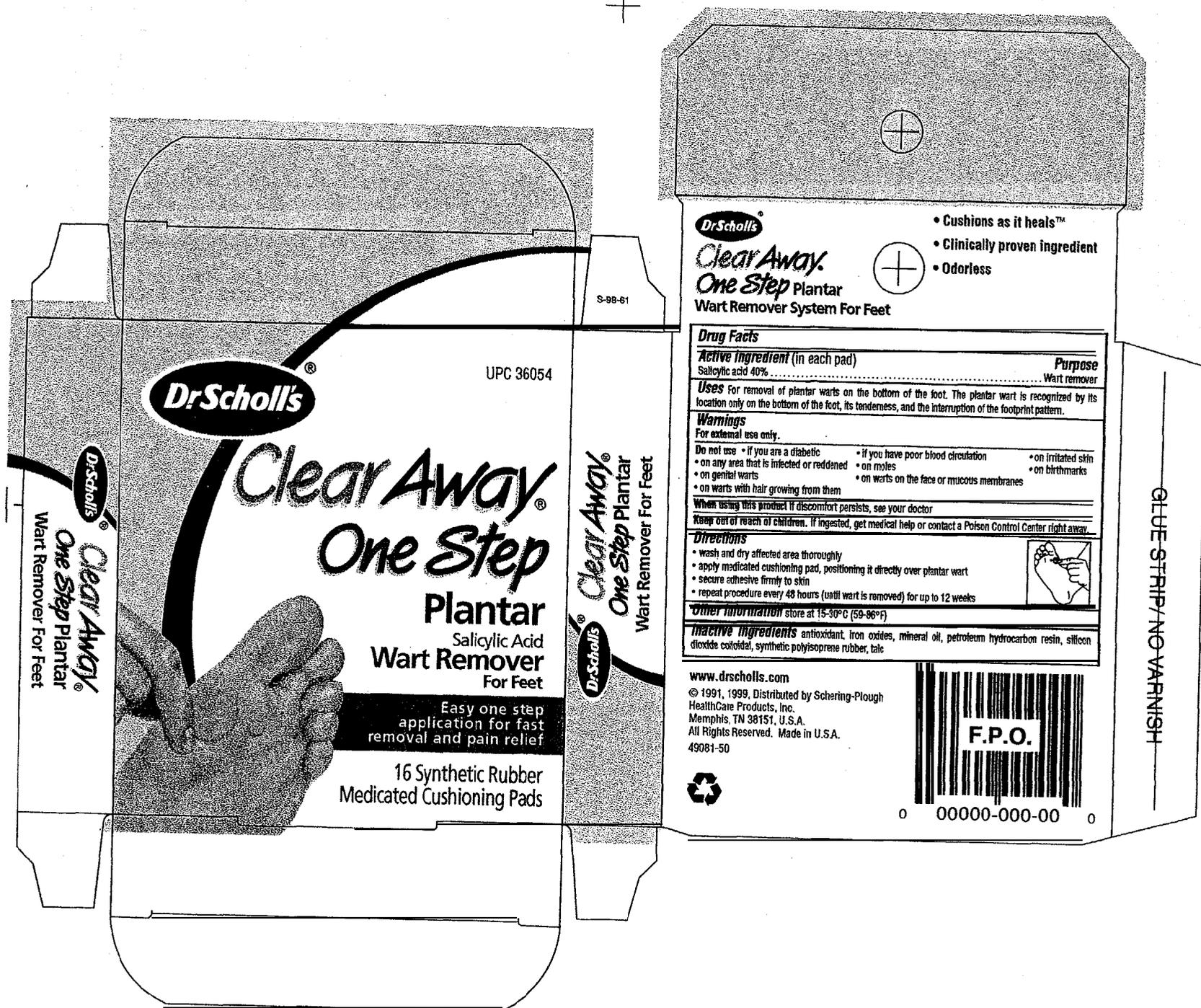
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GLUE STRIP/NO VARNISH



DrScholl's

UPC 36054

**Clear Away[®]
One Step[®]
Plantar
Salicylic Acid
Wart Remover
For Feet**

DrScholl's[®]
**Clear Away[®]
One Step[®] Plantar
Wart Remover For Feet**

DrScholl's[®]
**Clear Away[®]
One Step[®] Plantar
Wart Remover For Feet**

Easy one step application for fast removal and pain relief

16 Synthetic Rubber Medicated Cushioning Pads

DrScholl's

**Clear Away[®]
One Step[®] Plantar
Wart Remover System For Feet**



- Cushions as it heals™
- Clinically proven ingredient
- Odorless

Drug Facts

Active Ingredient (in each pad)	Purpose
Salicylic acid 40%	Wart remover

Uses For removal of plantar warts on the bottom of the foot. The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern.

Warnings

- For external use only.
- Do not use**
- if you are a diabetic
 - on any area that is infected or reddened
 - on genital warts
 - on warts with hair growing from them
 - if you have poor blood circulation
 - on moles
 - on warts on the face or mucous membranes
 - on irritated skin
 - on birthmarks

When using this product if discomfort persists, see your doctor

Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away.

Directions

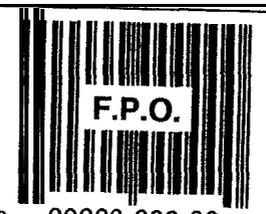
- wash and dry affected area thoroughly
- apply medicated cushioning pad, positioning it directly over plantar wart
- secure adhesive firmly to skin
- repeat procedure every 48 hours (until wart is removed) for up to 12 weeks



Other information store at 15-30°C (59-86°F)

Inactive ingredients antioxidant, iron oxides, mineral oil, petroleum hydrocarbon resin, silicon dioxide colloidal, synthetic polyisoprene rubber, talc

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GLUE STRIP/NO VARNISH

FedEx USA Airbill

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8156 6470 6180

Form 10, No.

0215

Recipient's Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records. FedEx Tracking Number 815664706180

Date 11/22/99

Sender's Name Dr Bill Soller Phone 202 429-9260

Company CONSUMER HEALTHCARE PROD ASSN

Address 1150 CONNECTICUT AVE STE 1200 Dept./Floor/Suite/Room

City WASHINGTON State DC ZIP 20036

2 Your Internal Billing Reference LABELING

3 To Recipient's Nameockets Magnonx Brand Phone 301 827 6860

Company FDA

Address 5630 FISHERS LANE ROOM 1061 Dept./Floor/Suite/Room

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To "HOLD" at FedEx location, print FedEx address here. City ROCKVILLE State MD ZIP 20852



4a Express Package Service

- FedEx Priority Overnight Next business morning
- FedEx Standard Overnight Next business afternoon
- FedEx First Overnight Earliest next business morning delivery to select locations
- FedEx 2Day* Second business day
- FedEx Express Saver* Third business day

Packages up to 150 lbs. Delivery commitment may be later in some areas.

* FedEx Letter Rate not available. Minimum charge: One pound rate

4b Express Freight Service

- FedEx 1Day Freight* Next business day
- FedEx 2Day Freight Second business day
- FedEx 3Day Freight Third business day

Packages over 150 lbs. Delivery commitment may be later in some areas.

* Call for Confirmation. * Declared value limit \$500

5 Packaging

- FedEx Letter*
- FedEx Pak*
- Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling

- Saturday Delivery Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- Sunday Delivery Available for FedEx Priority Overnight to select ZIP codes
- HOLD Weekday at FedEx Location Not available with FedEx First Overnight
- HOLD Saturday at FedEx Location Available for FedEx Priority Overnight and FedEx 2Day to select locations

- Does this shipment contain dangerous goods? One box must be checked.
- No
 - Yes As per attached Shipper's Declaration
 - Yes Shipper's Declaration not required
 - Dry Ice Dry Ice, 3, UN 1845 x kg
 - Cargo Aircraft Only
- Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment Bill to:

- Enter FedEx Acct. No. or Credit Card No. below.
- Obtain Recip. Acct. No.
- Sender Acct. No. in Section 1 will be billed.
- Recipient
- Third Party
- Credit Card
- Cash/Check

Total Packages	Total Weight	Total Charges
1	5	Credit Card Auth.

8 Release Signature

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Call 1-800-Go-FedEx (800-463-3339)

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