

*Joint Meeting of the National Transportation Safety Board  
and Food and Drug Administration on Transportation  
Safety and Potentially Sedating or Impairing Medications*

## **OTC Medications Labeling Considerations**

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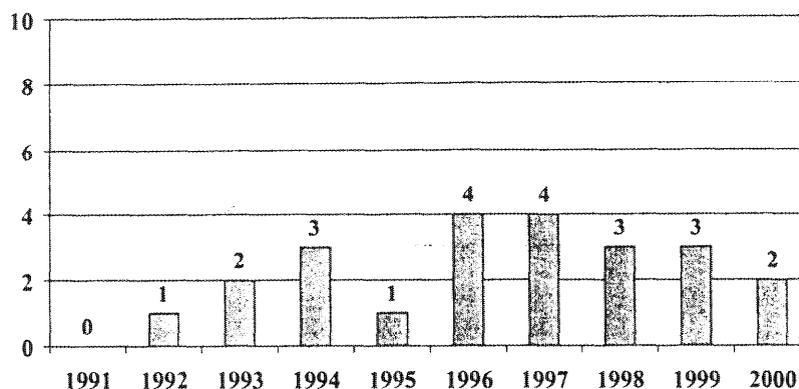
### **Outline**

- Overview
- OTC Drug Review Labeling: Drowsiness
- The New “Drug Facts” Label
- Public Education
- Conclusion

01N-0397

TS10

Total Adverse Experience Reports  
with an "Accident" Term for Persons  $\geq 16$  years of age



OTC and Rx AERs w/ AH as Primary Suspect (PS)	18
OTC and Rx AERs w/ AH as Secondary Suspect (SS)	5
OTC Packages Sold Over 10 years (1/1/91-12/31/00)/adults	~850 million

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## The OTC Label Core Elements of Information

**Active Ingredients**

**Uses**

**Warnings**

Absolute contraindications (Do not use...)

Relative contraindications (Ask a doctor before use...)

In-use precautions (When using ...)

**Directions**

**Other information**

**Inactive ingredients**

**Questions**

*Standardized  
Flow of information*



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*Standardized  
Flow of information*

*It's all important!*

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## Overview of OTC Labeling

### Example of Antihistamine Drowsiness Warning

Warnings for OTC Ethanolamine Antihistamines

Excerpt from the OTC "Drug Facts" Label

#### When using this product:

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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# New OTC Label

## Pre Drug Facts Label

**INDICATIONS:** Temporarily relieves runny nose and sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies.

**DIRECTIONS:** Follow dosage directions below, or use as directed by your doctor. Take every 4 to 6 hours. Do not take more than 6 tablets in 24 hours.

AGE	DOSAGE
adults and children 12 years of age and over	1 tablet
children under 12 years of age	Consult a doctor

**WARNINGS:** May cause excitability especially in children. Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery. 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.

**ACTIVE INGREDIENT:** Each tablet contains Ethanolamine x mg. Also contains (inactive ingredients are listed). Store at 59° to 77° in a dry place. Protect from light.

## Drug Facts

Active Ingredient (in each tablet)	Purpose
Ethanolamine x mg	Antihistamine

### Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

### Warnings

Ask a doctor before use if you have:

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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

When using this product:

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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

Take every 4 to 6 hours. Do not take more than 6 tablets in 24 hours.

AGE	DOSAGE
adults and children 12 years of age and over	1 tablet
children under 12 years of age	Consult a doctor

### Other Information

Store at 59° to 77° in a dry place. Protect from light.

**Inactive Ingredients** (inactive ingredients are listed)

Questions?

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# Education

- **Core Message**

- “Read the Label” .... i.e., Read the *entire* label

- **“Drug Facts” Box**

- Allows a renewed emphasis of core message

- Consumer friendly, easier to read, more prominent warnings

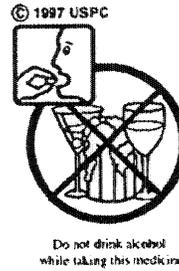
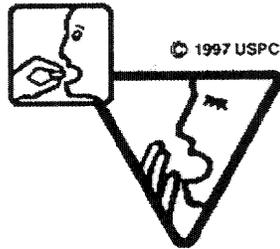
- **Awareness and Education**

- Targets: Operators and consumers

- CHPA Partnerships

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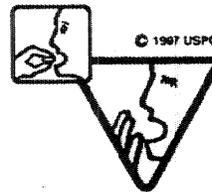
## The Question of Pictograms and Symbols



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## Pictograms and Symbols: *Thoroughly considered by FDA*

- Unproven in any in-use situation for OTCs
- Potentially open to considerable misinterpretation
- Cannot replace warning statements
- Lower literacy reader, still has to learn the language of pictograms
- Imply "all or nothing"
  - Thus, inaccurate if the warning expresses the possibility of a side effect

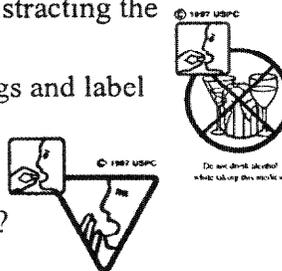


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## Pictograms and Symbols

### *Thoroughly considered by FDA*

- Crowd the label, making it less readable
- Work against the “Read the Label” message
  - Potentially interfere with the information flow of the OTC Drug Facts label by distracting the reader to start at the icon
  - ▶ May detract from other warnings and label information
- When would we stop?
  - A symbol for every warning...?



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## Conclusion

- OTC antihistamines have a demonstrated history of safe and effective use, when used according to label directions. They are appropriately and adequately labeled.
- Pictograms and symbols are unproven in any use situation for OTC medicines.
- CHPA believes that it is important to maintain an ongoing program of consumer education on the importance of reading the label.

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