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

2

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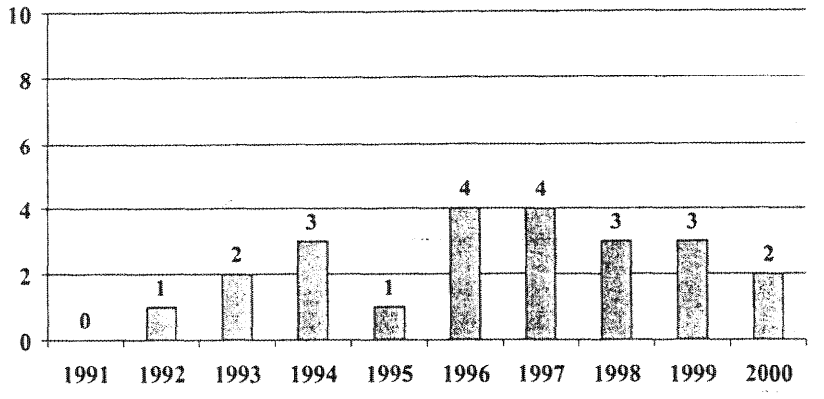
Total Adverse Experience Reports
with an "Accident" Term for Persons ≥ 16 years of age



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

3

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

4

The OTC Label
Core Elements of Information

Active Ingredients
Uses
Warnings
- Absolute contraindications
- Relative contraindications
- In-use precautions

Directions
Other information
Inactive ingredients
Questions

It's all important!

Standardized Flow of information

5

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

6

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

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°F in a dry place
- protect from light

Inactive ingredients (inactive ingredients are listed)

Questions?

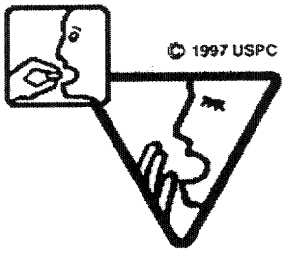
7

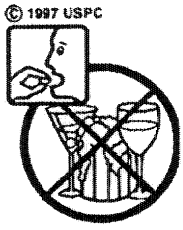
Education

- **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

8

The Question of Pictograms and Symbols

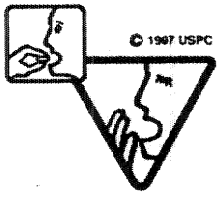




Do not drink alcohol while taking this medicine

9

Pictograms and Symbols:
Thoroughly considered by FDA



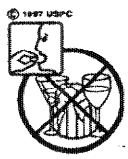
- Unproven in any in-use situation for OTCs
- Potentially open to considerable misinterpretation
- Cannot replace warning statements
- Lower literacy reader, still has to learn the language of pictograms
- Imply "all or nothing"
  - Thus, inaccurate if the warning expresses the possibility of a side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

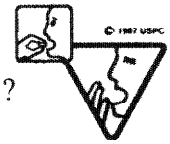
10

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…?





11

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.

12