

# **NDA/PADAC Joint Meeting**

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# OTC Issues: U.S. Regulations, Foreign Marketing, and Label Comprehension Study Results

# Content

- U.S. regulations regarding OTC anti-histamines
- Foreign marketing of loratadine
- Summary of label comprehension study



# OTC Drug Monograph Process

- Advance Notice of Proposed Rulemaking (ANPR)

*Advisory Review Panel Report*

- Tentative Final Monograph (TFM)
- Final Monograph (FM)



# OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products

## ANPR (1976)

- Advisory Review Panel Report
  - Does not mention CIU or hives

## TFM for OTC Antihistamine Drug Products (1985)

- One comment requested hives indication
  - No data submitted
  - Panel did not review hives



# Final Monograph for OTC Antihistamine Drug Products (1992)

- One comment recommended “symptomatic treatment of allergic itching”
- One comment referenced data supporting relief of itching skin caused by . . . hives
  - Hives are component of anaphylactic reaction
  - Average person cannot distinguish mild and life-threatening condition with similar symptoms
  - Cited reference states ideal urticaria treatment is removal of cause



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# Foreign Marketing of Loratadine

- Prescription required in 80 countries
- Prescription-free in 33 countries
  - 29 countries allow hives indication
    - 22 countries sell “behind-the-counter”
    - 7 countries sell over-the-counter  
Belgium, Canada, Germany, Ireland,  
the Netherlands, Russia, and United Kingdom



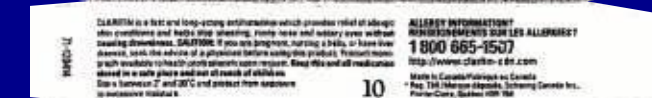
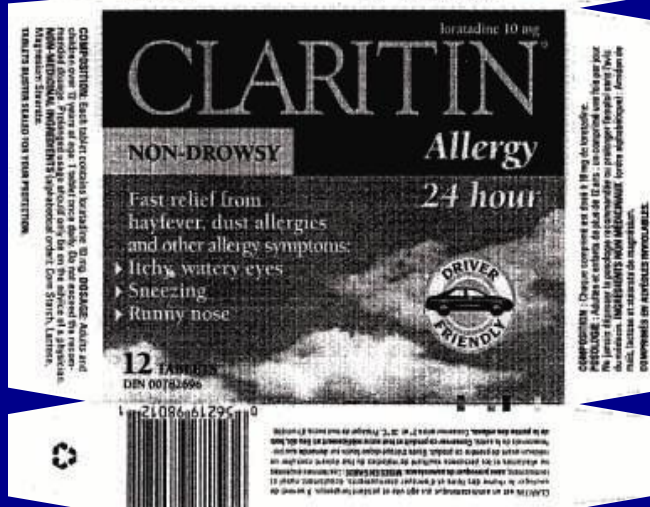
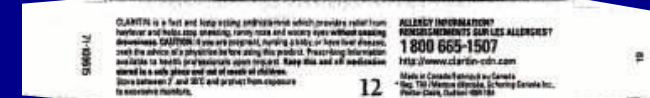
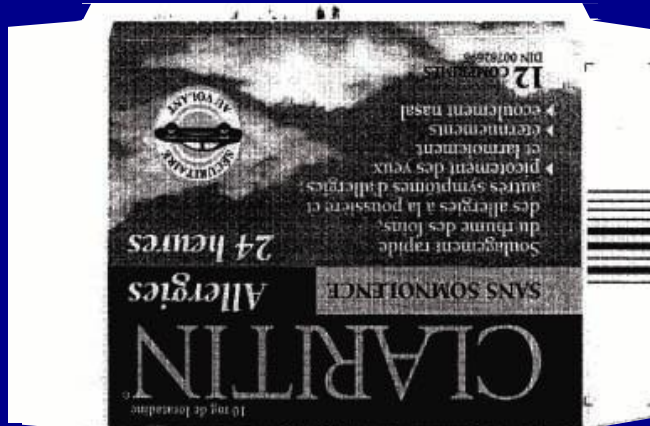


# Marketing of Loratadine in Canada

- Marketed OTC since 1990
- OTC indications: allergic rhinitis and hives



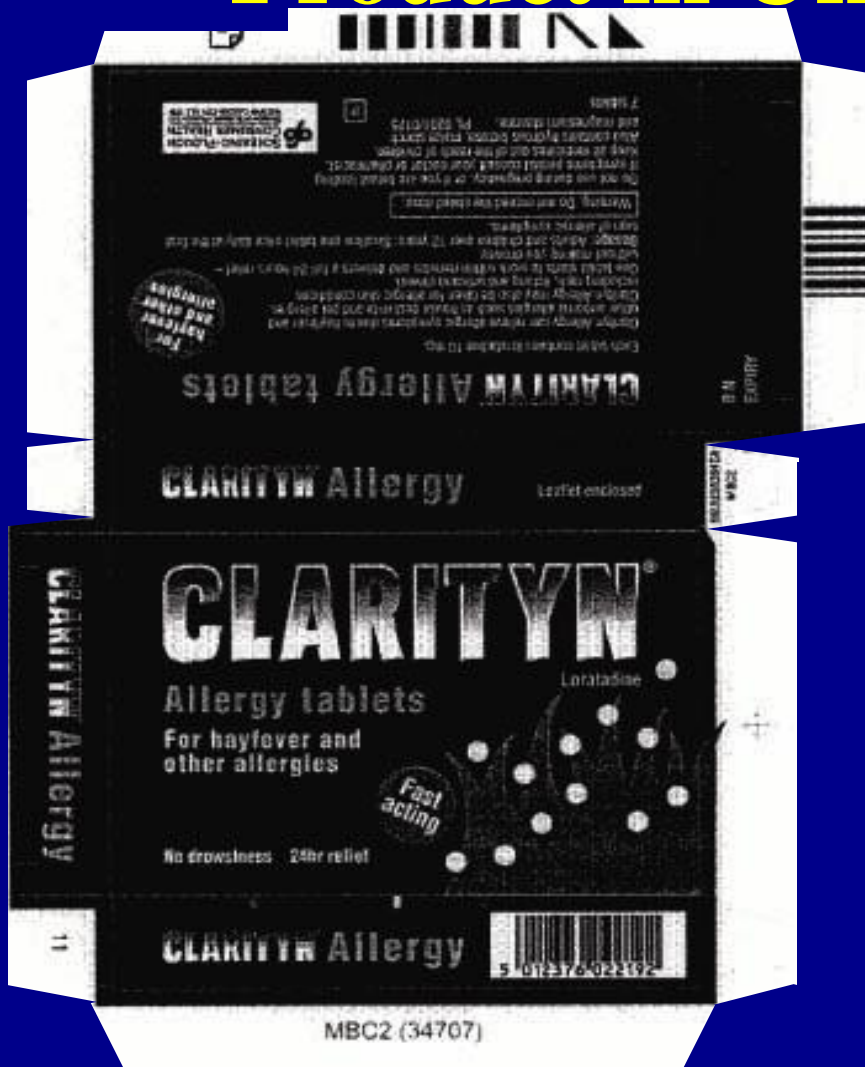
# Sample Labels of Selected Loratadine Products in Canada



# Marketing of Loratadine in United Kingdom

- Marketed General Sales List (GSL) since December 2001;  
previously Pharmacy (P) class
  - *GSL sales limited to 7 tablets*
- OTC indications: allergic rhinitis and hives
- Cetirizine only other GSL oral antihistamine with hives indication

# Sample Label of Selected Loratadine Product in United Kingdom



Clarityn Allergy may also be taken for allergic skin conditions including rash, itching and urticaria (hives).

# Summary of Sample Labeling Available from 19 Prescription-Free Countries

- chronic urticaria of unknown source: 1 country
- chronic urticaria and/or hives: 12 countries
- urticaria or hives: 3 countries
- allergic skin condition and urticaria: 3 countries
- “after being told by doctor”: 0 countries

**50% of cartons do not list indication**

# Loratadine Label (U.S.) Proposed by Sponsor



## Uses

- relieves and reduces itching and rash due to recurring or chronic hives of an unknown source.
- use only after being told by a doctor that you have recurring or chronic hives (chronic idiopathic urticaria).



# Loratadine Label (U.S.)

## Proposed by Sponsor



### Uses

- relieves and reduces itching and rash due to recurring or chronic hives of an unknown source; however, only use this product for itching and rash after being told by a doctor that you have recurring or chronic hives (chronic idiopathic urticaria).

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# CIU Self-Recognition and Label Comprehension Study

565 subjects

- Cohort 1: self-recognized CIU sufferers (N=196)
- Cohort 2: general population (N=116)
- Cohort 3: low literacy (N=96)
- Cohort 4: pregnant/nursing, liver/kidney disease (N=114)
- Cohort 5: acute hives sufferers (N=102)



# Label Comprehension Results

Based on the label, what is this product used for?

- 62% correct or acceptable response
  - 79% incorrect responses mentioned hives
  - Other incorrect responses: trouble speaking/swallowing, drooling, food or medication allergy, fever, breathing problems

# Label Comprehension Results

Is this product intended to be used for the following conditions?

	Total	CIU	Gen. Pop.	Low Lit.	Preg./ Liver/ Kidney	Acute Hives
Recurring or chronic hives of an unknown cause	92%	99%	85%	84%	90%	92%
Food allergies	12%	7%	16%	14%	13%	21%
One time breakout of hives	32%	20%	42%	37%	38%	42%

\*Percentage represents those who believe product is used for listed indication.



# Self-Selection Results

Considering everything on the package label, is this product intended for **you**, **personally**, to take home and start using?

	CIU	Gen. Pop.	Low Lit.	Preg./ Liver/ Kidney	Acute Hives
Correct/acceptable response	100%	70%	65%	80%	54%

# Conclusion

- OTC oral antihistamines cannot be marketed currently for hives or CIU under monograph system
- Foreign Market
  - Chronic hives is the commonly labeled indication
  - Loratadine is typically marketed Rx or “behind-the-counter”
- Consumers will use for all types of hives

