20. OTHER

20.C. CIU LABEL COMPREHENSION STUDY REPORT

WEST Pharmaceutical SERVICES

Consumer Healthcare Research

Chronic Idiopathic Urticaria
Self-Recognition and Label Comprehension Study
Protocol No. 12171

Final Report

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1.0 Executive Summary

Urticaria is a common disorder with many etiologies and pathophysiologies. The condition has both an acute and chronic form. Chronic urticaria can be idiopathic and the estimated incidence of this condition in the population is less than 3%.

The study sponsor, Schering-Plough, has conducted a self-recognition and label comprehension study to assure that consumers can demonstrate an understanding of the label and package insert including self-selection and that CIU sufferers can accurately self-recognize the condition and symptoms upon recurrence, and likely properly self manage treatment.

The objectives of this study were to evaluate how well the average consumer understood the conditions (i.e. uses, warnings and directions) in which Claritin® 24 could be used based on his/her reading of the carton label and package insert.

In addition, this study was to determine if consumers who stated in their medical history that they have been diagnosed by a physician as having recurrent or chronic hives of unknown origin, chronic idiopathic urticaria (CIU) could:

1) Accurately self-recognize the condition and symptoms upon recurrence.

2) Demonstrate comprehension of the carton label and package insert including appropriate selection for OTC Claritin® use.

This was designed to compare the accuracy of the consumer's self-recognition of recurrent or chronic hives of unknown origin to an assessment by a qualified study physician. This assessment was based on a discussion with the subject, their medical history, and in some cases, photographs of whealing/rashes. Secondarily, the consumer's ability to understand specific communication points on the label and package insert was studied.

This study included five (5) cohorts:

1) Cohort 1= CIU sufferers
2) Cohort 2= General Population
3) Cohort 3= Low literate
4) Cohort 4 = "Ask a doctor before use": Subjects that were either pregnant, nursing/breast-feeding or had liver or kidney disease.
5) Cohort 5 = "Do not use": Acute urticaria sufferers

Subjects in Cohort 1 (Self-recognized CIU) completed both arms of the study: label comprehension and self-recognition. Subjects in Cohorts 2 through 5 completed only the label comprehension arm of the study.

Interviewing for this study began on November 14, 2001 and ended on December 12, 2001. A total of 565 subjects were interviewed as follows:

- CIU Sufferers=196
- General population = 116
- Low literate = 96
- "Ask a doctor first" = 114
- "Do not use" = 102.

1.1 Key Findings

1.1.1 Self-Recognition

Subjects demonstrated the ability to self-recognize CIU. Nearly all (94%) of the subjects were confirmed by the physician as having CIU.

1.1.2 Label Comprehension – Package Label

1.1.2.1 Product use

When asked on an open-ended basis what the product was used for, CIU sufferers demonstrated the strongest understanding (77% correct/acceptable) of the 5 cohorts. The other cohorts scored below this level (range of 49% to 58% correct/acceptable). The most common incorrect

answer (mentioned by 20% of subjects) was "hives/itching due to hives." However, it is worth noting that it is extremely difficult to elicit a very specific answer (i.e. chronic hives/hives of an unknown source) from subjects in an open-ended question such as this.

When presented with a list of correct and incorrect product use conditions and asked to select the conditions for which the product is intended to be used, CIU sufferers demonstrated the strongest understanding (71% correct/acceptable) of the 5 cohorts. The other cohorts scored below this level (range of 38% to 49% correct/acceptable). Overall, most of the subjects (92%) stated this product is intended for recurring or chronic hives of an unknown cause, but were not considered "correct/acceptable" because they also stated it is indicated for other incorrect conditions. Nearly one-quarter (22%) stated this product is intended for hay fever.

However, subjects demonstrated a stronger understanding of the uses of Claritin® (66% - 99% correct/acceptable range across scenarios and cohorts) when presented with correct and incorrect usage scenarios.

1.1.2.2 Self-Selection

"Okay to use" (CIU Sufferers)

- All of the CIU sufferers (100%) for whom drug use was appropriate (i.e., who were "okay to use the product") correctly self-selected the product for their use or stated they would ask their doctor prior to use.

"Ask a doctor first" and "Do not use" (liver/kidney disease and pregnant/nursing, acute hive sufferers, not experience hives)

- The majority (80%) of the subjects who should "ask a doctor before using" this product understood this warning and either correctly stated they would ask a doctor before using it or they did not select the product as one they could use.
- Almost three-fourths (70%) of the general population and more than two-thirds (65%) of the low literate population who were not appropriate

candidates for Claritin® understood this and either correctly de-selected the product or stated they would "ask a doctor" prior to use.

- More than half (54%) of the subjects who suffer from acute hives and should "not use the product" either correctly de-selected the product or stated they would "ask their doctor" prior to use. Comprehension scores among this population improved (75%) for the direct scenario regarding use of the product for acute hives.

1.1.2.3 Warnings

Consumers across all cohorts demonstrated a strong understanding (75% - 100%) of all the warnings. Notably, CIU sufferers demonstrated a strong understanding that this product should not be used in situations in which serious symptoms (e.g., trouble swallowing, wheezing or problems breathing, etc.) are present (91% and 96% correct/acceptable for the two scenarios that addressed this objective).

1.1.2.4 Directions

Overall, subjects demonstrated a strong understanding (67% - 100%) of all the directions for use. Regarding the direction of not taking more than one tablet in a 24 hour period, the low literate population's understanding of this was somewhat less (78%) than the other cohorts.

1.1.3 Label Comprehension – Package Insert

Subjects demonstrated strong understanding (84% - 99%) that Claritin® is not indicated for acute hives. Most subjects (90% - 96%) understood when to stop taking Claritin® after the itching stops. Comprehension was lower (57% - 81%) regarding the implications of taking more than one tablet within 24 hours, especially among the low literate (57%).

1.2 Conclusions

1.2.1 Self-Recognition

- CIU sufferers can accurately self-recognize (94%) the condition and symptoms of CIU upon recurrence.

1.2.2 Label Comprehension

Overall, consumers understood the uses of Claritin®, the label warnings, and directions with the exception of those findings noted below.

- When presented with correct and incorrect product use situations in scenarios, non CIU sufferers demonstrated a strong understanding (66% - 97%). However, this level decreased (38% - 58%) when subjects were asked about the uses of the product on an open-ended basis. The most common incorrect answer (mentioned by 20% of subjects) was "hives/itching due to hives."
- When presented with a scenario of acute hives, three-fourths (75%) of acute hive sufferers understood Claritin® is not indicated for this condition. When acute hive sufferers were asked whether Claritin® is intended for their use, more than half (54%) either correctly de-selected the product or indicated they would ask their doctor prior to use.

2.0 Introduction

Urticaria is a common disorder with many etiologies and pathophysiologies. The condition has both an acute and chronic form. Chronic urticaria can be idiopathic and the estimated incidence of this condition in the population is less than 3%.

Loratadine 10mg tablets were first introduced in the United States as a prescription medicine in 1993 under the brand name of Claritin®. Loratadine is indicated in the treatment of chronic idiopathic urticaria (CIU) as well as the treatment of seasonal allergic rhinitis (SAR).

The study sponsor, Schering-Plough, conducted a self-recognition and label comprehension study to assure that consumers can demonstrate an understanding of the label and package insert including self-selection and that CIU sufferers can accurately self-recognize the condition and symptoms upon recurrence, and likely be able to self manage treatment..

3.0 Objectives

The objectives of this study were to evaluate how well the average consumer understood the conditions (i.e. uses, warnings and directions) in which Claritin® could be used based on his/her reading of the carton label and package insert.

In addition, this study was to determine if the subset of consumers who claimed they have been diagnosed by a physician as having recurrent hives or chronic hives of unknown origin, chronic idiopathic urticaria (CIU) could:

1) Accurately self-recognize the condition and symptoms upon reoccurrence.

2) Demonstrate comprehension of the carton label and package insert including appropriate selection for OTC Claritin® use sufficiently to self treat without physician involvement. (See Labeling :Appendix 8.4)

3.1 Key Label Communication Objectives that were Evaluated:

1) Consumers understand the **uses** of the product.

   a. Claritin® relieves and reduces itching and rash due to recurring or chronic hives of an unknown source (chronic idiopathic urticaria).

   b. Claritin® should be used only after being diagnosed by a doctor for recurrent or chronic hives.

2) Consumers understand the **warnings** of the product.

   c. Seek emergency medical attention if any of the following symptoms occur along with a rash, hives or an insect bite or sting: trouble swallowing; fever above 100°F; wheezing or problems breathing; hives or swelling in or around mouth; drooling; trouble speaking; joint pain

3) Consumers understand who can and cannot use Claritin® **(warnings)**.

   d. Do not use if you are allergic to Claritin® (Loratadine) or other antihistamines.

e. Do not use for allergic skin reaction or hives unless you have been told by a doctor that you have recurring or chronic hives of an unknown source (chronic idiopathic urticaria).

f. Do not use to treat food allergies or insect bites or stings.

4) Consumers understand under what conditions one must first ask their doctor before using Claritin® **(warnings)**.

g. Ask a doctor before use if you have liver disease.

h. Ask a doctor before use if you have kidney disease.

i. Ask a doctor before use if you are pregnant or breast-feeding.

j. Do not give to children under 6 years of age unless directed by a doctor.

5) Consumers understand the conditions under which Claritin® should be used **(warnings)**.

k. Ask a doctor if your itching or rash due to chronic or recurring hives do not improve after 5 days of treatment.

6) Consumers understand the **directions** for use.

l. Adults and children 6 years and over: 1 tablet every 24 hours.

m. Do not exceed 1 tablet in 24 hours.

n. Children under 6 years of age, ask a doctor.

3.2 Key Package Insert Communication Objectives to be Evaluated:

1) Consumers understand who should not take Claritin®.

a. People suffering from "Acute" Urticaria or hives caused by a reaction to food or drugs, insect stings or bites, stress or other known causes.

2) Consumers understand the directions for using Claritin® safely and effectively.

b. Taking more than one tablet in 24 hours can cause drowsiness.

c. Stop taking Claritin® 5 days after the itching stops.

4.0 Study Plan

4.1 Study Design

This was a multi-center study to compare the accuracy of the consumer's self-recognition of recurrent or chronic hives of unknown origin to an assessment by a qualified study physician. This assessment was based on a discussion between the subject and the study physician regarding the subject's medical history, and in some cases, photographs of whealing/rashes. Secondarily, the consumer's ability to understand specific communication points on the label and package insert was studied.

Subjects were asked to read the package label for Claritin® as if they were in the store considering whether to purchase the product for their own personal use. They were told that after they read the label, they would be asked questions about it, but they would be able to refer to the label as needed.

For a portion of the interview, subjects were given a series of scenario cards that described people in different situations with varying medical conditions. They were told to refer to the label and state whether this product is intended to be used in the situation described.

This study involved a single study visit to the research site. No drug was dispensed during the study.

This study included five (5) cohorts:

1) Cohort 1= CIU sufferers
2) Cohort 2= General Population
3) Cohort 3= Low literate
4) Cohort 4 = "Ask a doctor before use": Subjects that were either pregnant, nursing/breast-feeding or had liver or kidney disease.
5) Cohort 5 = "Do not use": Acute urticaria sufferers

4.1.1 Self-Recognition

Subjects in Cohort 1 (Self-recognized CIU) completed both arms of the study: label comprehension followed by study physician assessment of the subject's ability to self-recognize CIU.

In order for the subjects to be evaluated on their ability to self-recognize chronic idiopathic urticaria, they underwent a process that allowed them to speak with a nurse and a physician at West's Central Medical Operations Group (CMOG). There were two physician roles in this study, a CMOG study physician and a coordinating dermatologist. A CMOG study physician spoke with each of the subjects over the telephone. Based on the conversation with the subject, a review of the subject's medical history, and in some cases, photographs of the subject's lesions, the study physician assessed whether he/she believed the subject had correctly self-recognized CIU. The coordinating dermatologist reviewed all of the subject data to conclude if the subject accurately self-recognized CIU.

4.1.1.1 Self-Recognition Arm Process

1) Subjects completed a self-administered medical history. (See Appendix 8.5.3)

2) Subjects were asked to sign a Limited Release of Medical Information Consent form. The consent permitted a Schering-Plough physician to contact the respondents' personal physician for additional information if needed. Consent was limited to the collection and confirmation of information regarding the respondent's chronic idiopathic urticaria.

3) If the subjects were currently experiencing wheals or other symptoms of CIU, the marketing research staff at each facility obtained a photo consent from the subjects and then took a picture of the subjects' wheals.

4) The signed Release of Information Form, Informed Consent and Self-Reported Medical History Form were faxed to the study physician.

5) A nurse reviewed the subjects' medical history and clarified any issues as needed.

6) The study physician reviewed these documents with the subjects and asked the subjects questions necessary to frame a history of CIU. (See Section 6.1)

7) For subjects who did not present with whealing or any obvious symptoms, refused photo consent, or had a photo taken that was of poor photographic quality, the study physician determined accuracy of their self-recognized CIU based on medical history and the subjects' selection of a photograph that best represented their skin lesions when they experience CIU. Specifically, the subjects were shown two alternative photographs of skin rashes (i.e., chronic urticaria and poison ivy). They were asked to select the letter code of the photograph that looked the most like the rash for which they suffer CIU. Their response was recorded on the Self-Administered Medical History Form that was sent to the coordinating dermatologist. (Appendix 8.5.5)

8) The site research staff sent the subjects' CIU photo to the coordinating dermatologist at West.

9) The coordinating dermatologist reviewed all subjects' medical history, the photo (if taken), and the selected rash photograph to confirm the study physicians' conclusions. (Note: in almost all cases, the pictures taken were of poor photographic quality. Thus, the coordinating dermatologist seldom used the photos in the final conclusion.)

4.1.2 Label Comprehension

All subjects completed the label comprehension arm of the study. Subjects in Cohort-1 (*CIU Sufferers*), Cohort 2 (*General Population*), Cohort 3 (*Low Literacy*), and Cohort 5 ("*Do not* use") completed the full label comprehension questionnaire. Subjects were given scenarios that reflected

actual sufferers of CIU and then were asked questions relating to the label and package insert key communication objectives.

Subjects in Cohort 4 (*"Ask a doctor before use"*) answered a shortened version of the questionnaire. The main purpose of this interview was to determine if consumers who were pregnant/nursing or had a liver or kidney disease understood that they need to ask a doctor before using Claritin® when asked to assume they had been diagnosed by a doctor as having CIU. All subjects were told to refer back to the label and package insert as often as needed.

4.1.2.1 Label Comprehension Arm Process:

1) Subjects completed the REALM test.
2) Subjects read the proposed label.
3) Subjects participated in a label comprehension interview administered by an trained interviewer.
4) Subjects read the package insert.
5) Subjects participated in a package insert comprehension interview administered by a trained interviewer.

4.2 Study Population

4.2.1 Source and Number of Subjects

A total of 565 subjects were interviewed for this study. The population consisted of adult males and females, 18 years of age and older. An enriched population of adults 18 years of age and older were included for Cohorts 1, 3, 4, and 5.

1) Chronic Idiopathic Urticaria (CIU) Sufferers (n=196)

   This population was pre-recruited through advertising and direct mail and then screened for participation.

2) General Population (n=116)

This population was recruited via mall intercept in a broad U.S. market distribution to ensure a wide range of socio-economic and educational levels.

3) Low Literate (n=96)

All subjects were required to take the REALM (Rapid Estimate of Adult Literacy in Medicine) test to determine reading literacy. Low literate is defined as a subject who reads at a maximum grade equivalent of seventh-eighth grade or below as measured by the REALM literacy-screening instrument.

Subjects in other cohorts who were low literate also counted towards this cohort. The remaining consumers for this cohort were recruited and interviewed at off-site locations known to have a higher concentration of low literate adults, such as neighborhood grocery stores, convenience stores and apartment complexes.

4) *"Ask a doctor before use"* (liver or kidney disease/pregnant or nursing) (n=114)

This cohort included subjects who were pregnant, nursing, or had liver or kidney disease. Subjects who were pregnant/nursing were recruited via mall intercept. Those subjects who had liver or kidney disease were pre-recruited at special sites and by using agency databases, and asked to come to a central location for the label interview.

5) *"Do not use"* (Acute hive sufferers) (n=102)

This cohort included subjects who had self-reported acute urticaria. These subjects were recruited via mall intercept.

4.2.2 Inclusion Criteria

4.2.2.1 Cohort 1: Chronic Idiopathic Urticaria (CIU) Sufferers

1) Males or females, of any race, and at least 18 years of age.

2) Consumers with self-reported CIU that had been previously diagnosed by a physician.

4.2.2.2 Cohort 2: General Population

1) Males or females, of any race, and at least 18 years of age.

4.2.2.3 Cohort 3: Low Literate

1) Males or females, of any race, and at least 18 years of age.
2) Read at a maximum 7th-8th grade equivalency level (raw score of 60 or lower) as determined by the Rapid Estimate of Adult Literacy in Medicine (REALM) literacy screening instrument.

4.2.2.4 Cohort 4: "Ask a doctor before use" Consumers: Subjects who were Pregnant/Nursing or had Liver or Kidney Disease

1) Males or females, of any race, and at least 18 years of age.
2) Consumers who were currently pregnant and/or nursing or had liver or kidney disease.

4.2.2.5 Cohort 5: "Do not use" Consumers: Acute Urticaria Sufferers

1) Males or females, of any race, and at least 18 years of age.
2) Consumers who had self-reported acute urticaria (i.e., there is a known cause for hives, they had suffered for less than six weeks, etc.).

4.2.3 Exclusion Criteria

Subjects in all cohorts were excluded from the study if:

1) The subject or an immediate family member was employed in the healthcare industry as a doctor, nurse, pharmacist or laboratory technician or was an employee of a pharmaceutical company or a managed care / health insurance company.
2) They normally wear corrective lenses, contacts or glasses *to read* and did not have them or had any other visual impairment that prevented them from being able to read the label and package insert.

4.2.4 Study Dates

Interviewing for this study began on November 14, 2001 and ended on December 12, 2001.

4.2.5 Subject Disposition

A total of 565 subjects were interviewed for this study, distributed among the cohorts as shown below.

Table A: Final Sample Size Within Cohorts

	Total	CIU Sufferers	General Population	Low Literate Population	"Ask a Dr. first" Preg/Nsg./ Liver/ Kidney	"Do not use" Acute Hive Sufferers
Completed Interviews	565	196	116	96	114	102

The number of interviews conducted in each cohort does not add to the "total" as subjects could count toward more than one cohort.

4.2.6 Sample Size

4.2.7 Cohort 1: CIU Sufferers

Assuming a hypothesized proportion of 80%, a sample size of 200 would yield an error range of + / - 5.7% at the 95% confidence level in a large population.

4.2.8 Cohort 2: General Population; Cohort 4: "Ask a doctor before use"; and Cohort 5: "Do not use"

Assuming a hypothesized proportion of 80%, a sample size of 100 would yield an error range of + / - 7.88% at the 95% confidence level in a large population.

4.2.9 Cohort 3: Low Literate

Assuming a hypothesized proportion of 65%, a sample size of 100 would yield an error range of +/- 9.3% at the 95% confidence level in a large population.

4.2.10 Study Location

Twenty-four (24) marketing research facilities located in twenty-one (21) geographically dispersed markets across the United States were used to complete recruiting and enrollment for this study.

Twenty (20) of the sites conducted interviews via the shopping mall intercept method to recruit subjects for Cohort 2 - General population, Cohort 4 – "Ask a doctor before use" (pregnant/nursing subjects only), and Cohort 5 - "Do not use": Acute hives. Because of the need to pre-recruit Cohort 1 - CIU Sufferers, these same 20 mall sites also conducted telephone interviews to screen subjects who responded to a newspaper or radio advertisement. If, based on the screening questionnaire, the subjects qualified for Cohort 1, they were scheduled for an appointment at the research site to undergo the interview process.

Three (3) off-site locations conducted interviewing for Cohort 3 - Low Literate. Low literate recruiting was conducted in facilities such as convenience stores, grocery stores, apartment complexes, and other locations that provide a higher concentration of low literate adults.

Three (3) other off-site locations conducted the interviewing for Cohort 4 – "Ask a doctor before use" (liver/kidney disease subjects only). Those subjects who had liver or kidney disease were pre-recruited at these sites as well as by agency databases, and asked to come to a central location for the label interview.

This study was conducted in the following markets:

Table B: Market Research Agency Locations

Cohort 1: CIU Sufferers **Cohort 2: General Population** Cohort 4: "Ask a Dr. First": (Pregnant/Nursing) **Cohort 5: "Do not use": Acute Hives**	**Cohort 3: Low Literate Population**	Cohort 4: "Ask a Dr. first": **(Liver/Kidney Disease)**
Mall Intercept & Telephone Pre-Recruit (n=20 locations)	Off-Site Recruiting (n=3 locations)	Telephone Pre-Recruit (n=3 locations)
Boise, ID	Jacksonville, FL	Baltimore, MD
Boston, MD	Los Angeles, CA	Chicago, IL
Chicago, IL	Memphis, TN	Los Angeles, CA
Colorado Springs, CO		
Dallas, TX		
Detroit, MI		
Indianapolis, IN		
Jacksonville, FL		
Los Angeles, CA		
Memphis, TN		
Milwaukee, WI		
Minneapolis, MN		
New York, NY		
Oklahoma City, OK		
Orlando, FL		
Philadelphia, PA		
Portland, OR		
San Francisco, CA		
Springfield, IL		
Syracuse, NY		

5.0 Data Management

The completed questionnaires were shipped from the sites to West for data entry. All data was entered using the double data entry verification process. All verbatim responses were reviewed and classified into appropriate codes. Tabulations were developed and used for analysis.

5.1 Verbatim Coding Process

An initial sample of verbatim comments was pulled from the first 20% of the completed questionnaires. A data coordinator reviewed the verbatim comments and created "codes" for each verbatim comment. Additional codes were added as needed. To minimize coder bias and variability in the coding process, one individual coded all the completed questionnaires.

After completing the coding process, West and Schering-Plough divided these codes into "correct," "acceptable," and "incorrect" categories for each question. West and Schering-Plough agreed upon these category principles prior to the start of the data tabulation.

Summary tables were constructed that contain the number and percentage of "correct", "acceptable" and "incorrect" responses to each question for all of the study populations. In general, the "correct" and "acceptable" were combined and indicate positive label comprehension, while the "incorrect" responses indicate negative label comprehension.

A "correct" response is typically defined as either (1) a response that is initially answered correctly or (2) one that was initially an incomplete response, but a follow-up probe indicated correct action. An "acceptable" response is defined as a response that is not what the label directs, but would not be incorrect in terms of product usage. An "incorrect" response is defined as a response that indicates the subject did not understand the label.

5.2 Analysis of Self-Selection Question Series

The purpose of the "self-selection" series of questions was to determine if consumers understood whether they could use Claritin® based

on their personal history of hives, as well as their current medications and medical conditions.

Subjects were asked to review the label and "decide whether this product is intended for you, **personally**, to use." After allowing the respondent time to review the label, subjects were asked "Considering everything on the package label, is this product intended for **you, personally,** to take home and start using?" Because the intent of Cohort 4 ("Ask a doctor first": liver/ kidney/ pregnant/ nursing subjects) was to determine if subjects with these conditions understood the warning label and would either not use the product or ask their doctor first, these subjects were also asked to assume they had been told by their doctor that they have recurring hives or chronic hives of an unknown source.

As a follow-up to the self-selection question, everyone was asked to state their reason(s) for their answer. If a respondent stated a reason that clearly indicated the person did not understand the intent of the question (i.e. "unfamiliar/need to know more about it", "I don't have hives"), they were again provided an overview of the question and asked the Self-Selection question a second time. And, like the original question, as a follow-up all of these subjects were asked their reasons for their answer

To analyze their self-selection of the product, subjects were asked a series of medical history/health questions that determined if they had been diagnosed with CIU, had chronic hives, or had any of the contraindicated symptoms listed on the label (liver or kidney disease, pregnant or nursing). Based on their answers to these medical/health questions, as well as their history of hives, subjects were classified as "okay to use," "ask a doctor first," or "do not use." This is described in more detail in the following section.

5.2.1 Classification of Subjects

Subjects were classified as "okay to use," "ask a doctor first," or "do not use" based on the following:

5.2.1.1 "Okay to use" (CIU Sufferers)

Subjects in any of the cohorts were classified as "okay to use" if they met all of the following conditions:

1) Must have chronic idiopathic urticaria (confirmed in Cohort 1, self-reported in all other cohorts)
2) Not have liver or kidney disease
3) Not currently pregnant or nursing a child

5.2.1.2 "Ask a doctor first" (liver disease/kidney disease/pregnant/nursing)

Subjects in any of the cohorts were classified as "ask a doctor first" if they met all of the following conditions:

1) Have liver or kidney disease
2) Currently pregnant or nursing a child

Subjects in this classification did not have to have CIU as the self-selection question in this questionnaire version asked the subjects to assume they had been diagnosed by a doctor as having CIU.

5.2.1.3 "Do not use" (Not experience hives, experience acute hives)

Subjects in any of the cohorts were classified as "do not use" if they met all of the following conditions:

1) Did not state they were currently experiencing hives or had not experienced hives in the past 6 months, OR
2) Stated they were experiencing hives or had experienced hives in the past 6 months, but they had never been told by a doctor that they have recurring or chronic hives with an unknown cause (CIU)
3) Not have liver or kidney disease
4) Not currently pregnant or nursing a child

5.2.2 Categorization of Responses

Responses to the self-selection question were categorized as "correct", "acceptable" or "incorrect" based on the respondent classification as follows:

Table C: Categorization of Responses

Response to Self-Selection	Respondent Classification		
	Okay to Use	Ask Dr. First	Do Not Use
Okay to use	Correct	Incorrect	Incorrect
Okay if ask Dr. first	Acceptable	Correct	Acceptable
Not okay to use	Acceptable	Acceptable	Correct

5.3 Analysis of Direct Scenarios

The communication objectives for this label were addressed by giving subjects a scenario of a situation and having them determine the correct action one should take. Subjects read several scenarios describing different conditions that may limit use of the product, require specific action before using the product, or require specific action after using the product. Depending on the label warning, subjects were asked either whether it was "okay or not okay" for the person described to use the product, or what the person described in the scenario "should do now." Responses to the scenarios were coded as "correct", "acceptable" and "incorrect".

For the "okay/not okay" questions, those who initially answered incorrectly, or said "don't know", were asked a follow-up question of "Why do you say that?" The reasons given at this follow-up question were reviewed to make the final determination as to whether subjects were considered "correct", "acceptable" or "incorrect". For the "What should this person do now?" questions, those who did not initially give the correct action were probed with "what *else* should this person do now?" Again, the answers to both parts of the question, as well as the order the answers were given, were reviewed to make the final determination as to whether subjects were

considered "correct", "acceptable" or "incorrect". These types of follow-up questions are standard for label comprehension testing and were asked to ensure that the full range of comprehension was elucidated from the subjects.

5.3.1 Categorization of Responses

In general, responses to each scenario were categorized by the first "action" (e.g., call a doctor) mentioned by the respondent.

1) Correct:
   - Correct Initially: Initially answered correctly.
   - Correct After Probe: Initial response was not correct, but responses to follow-up questions indicated correct action.
2) Acceptable: responses that are not what the label directs, but would not be incorrect in terms of product usage (e.g., for a scenario where a person should not use the product, a response of "consult a doctor first" would be an acceptable action.)
   - Acceptable Initially: Initial response was acceptable
   - Acceptable After Probe: Initial response was not acceptable but answer to probe would be acceptable or indicated that respondent understood label warning.
3) Incorrect: initial response was incorrect and follow-up reason was incorrect, or first "action" was incorrect, even if subsequent actions mentioned were correct (e.g., use the product then ask my doctor).

The data tabulation located in Appendix 8.2 show the responses to the scenarios and include not only the net percent for correct, acceptable and incorrect, but also details of these responses. The responses are listed in the order in which subjects stated them.

6.0 Analytic Plan

6.1 Self-Recognition

During this study, the subjects in Cohort 1 (CIU Sufferers) completed a self-administered medical history with questions specifically targeted towards gathering information about the chronic idiopathic urticaria they experience.(Appendix 8.3.3) They were also shown two alternative photographs of skin rashes (i.e., chronic urticaria and poison ivy) and asked to select the letter code of the photograph that most looked like the rash they suffer with CIU. (Appendix 8.5.5) The subject's response was recorded on the self-administered medical history form and faxed to the Study physician. If the subject was currently experiencing hives at the time of the visit, they were asked to provide consent to allow a photograph to be taken of their hives/rash. The photo was taken and sent to West for review by the coordinating dermatologist.

The research site called the West Central Medical Operations Group (CMOG) to allow the subject to speak with the CMOG study physician. A discussion of the subject's CIU took place, and the following questions were asked in order to determine whether the subject had accurately self-recognized CIU:

1) Please describe the appearance of the hives you experience.
2) Do the hives always occur in the same place or do they vary in location?
3) Do the hives itch?
4) Are the hives raised and red or blister-like?
5) How long do the hives last?
6) Are the hives triggered or associated with anything you come in contact with?
7) Do you know what causes your hives?

8) Do your hives resemble any of the photos you were shown? If so, which one?

9) Have you been diagnosed with chronic idiopathic urticaria by a medical doctor?

10) Are you currently being treated for your hives?

Based on the subject's answers to these questions and the information gathered on the self-administered medical history, the CMOG physician made a determination of whether the subject had accurately self-recognized chronic idiopathic urticaria and entered this on the Medical History Review form (Appendix 8.5.3). In order to conclude that the subject had accurately self-recognized CIU, the physician reviewed the subject's answers and based their final determination on the following criteria:

6.1.1 Criteria Used to Determine Correct CIU Self-Recognition

1) Previously Diagnosed: The subject had to have been previously diagnosed by a physician as having chronic idiopathic urticaria or chronic hives of an unknown source.

2) Duration: The hives had to be caused by an unknown source and had to occur for a period longer than 8 weeks.

3) Hive Symptoms: The subject's description of his/her hives had to include "raised, flat, itchy, and/or red". If the subject described their hives as "blisters," clarification was requested. Note: it was often found that the subject did not mean a blister at all, and that they actually described a hive.

4) Location: The hives had to occur in various locations on the subject's body, not in one or two particular locations.

5) Chose Correct Photo: When shown the photos by the research site staff, the subject had to choose 'Photo Q" as the one that most looked like the hives they experience. If the subject chose the incorrect photo,

'Photo M', the CMOG physician probed further. Note: in some cases, the physician believed the subject still accurately self-recognized CIU.

6) Photo Taken: In cases when a photo was taken of the hives, the dermatologist used the photo to further assess the subject's self-recognition of CIU.

There were a few incidences when the study physician and the coordinating dermatologist did not agree on a subject's ability to self-recognize CIU. In these cases the coordinating dermatologist was the final authority and changed the study physician's assessment and noted the reason in the comment section on the Medical History Review Form.

6.2 *Label Comprehension*

The purpose of this arm of the study was to determine if the key label communication objectives from Section 2.0 have been met. A subject was considered to have successfully met a particular communication objective if, after probing, s/he presented a correct/acceptable response to the question related to that objective. The primary endpoints consisted of the percentage of subjects in each cohort (CIU Sufferers, General Population, Low Literate, "Ask a doctor first": Liver/kidney/pregnant/nursing, and "Do not use": acute hives) who successfully met each communication objective as stated in the protocol.

The primary statistical analysis consisted of point estimates for the proportion of subjects in all of the cohorts who successfully met each communications objective. A secondary analysis determined if there was a significant difference between the proportion of consumers in all five of the cohorts who met each communication objective. All proportions were tested using a t-test at the 95% level of confidence.

7.0 Results

7.1 *Self-Recognition*

Only those subjects in Cohort 1, CIU Sufferers (self-reported), participated in this arm of the study. In order for the subjects to be evaluated on the ability to self-recognize chronic idiopathic urticaria, they underwent a process (outlined in Section 4.1.1) that allowed them to speak with a nurse and a study physician at West's Central Medical Operations Group (CMOG).

Nearly all of the subjects (94%) who self-reported having CIU were confirmed by the physician as having CIU. (See Appendix 8.1 for the respondent data listings that outline subjects' answers to each of the medical questions outlined in Section 4.1.1 that led physicians to their conclusions.)

Table D: Self-Recognition

SELF-RECOGNITION Whether Consumers can accurately self-recognize the condition and symptoms of CIU upon recurrence.				
Objective	**Question #**	**Tab Page #**	**Cohort 1: CIU Sufferers %**	
			YES	**NO**
1. Consumers accurately self-recognize the condition and symptoms upon recurrence	MHR5.) Did the subject correctly self-recognize the hives and symptoms associated with CIU?	13	94	6

7.2 *Label Comprehension – Package Label*

7.2.1 Product Use

This objective was addressed via two different methods – direct questions and scenario based questions. First, subjects were asked directly to state, open-ended, the uses of the product (Q.1). In addition, a multiple choice question was asked in which a list of various conditions was shown to subjects and they were asked to state the conditions in which this product is intended to be used (Q.2).

Secondly, a series of scenarios were presented to subjects that described people with different situations of either CIU hives/rashes or non-CIU hives/rashes. For each scenario, subjects had to determine whether Claritin® is intended to be used in the situation described.

7.2.1.1 Direct Questions

On both direct questions (Q.1 & Q.2), to be considered "correct", subjects had to state specifically CIU or recurring/chronic hives, not just hives in general. In addition, subjects could not mention any incorrect condition. Those who mentioned CIU hives along with respiratory allergies, hay fever or animal allergies, were considered "acceptable", given Claritin's® current and extensive use for respiratory allergies. Subjects considered "incorrect" were those who mentioned CIU hives along with an incorrect product use (colds, other allergic reactions, etc.), just hives in general, or any other mention that did not include CIU hives.

When asked on an open-ended basis what the product is used for, CIU sufferers demonstrated the strongest understanding (77% correct/acceptable). The other cohorts scored lower (range of 49% to 58% correct/acceptable). The most common incorrect answer (mentioned by 20% of subjects) was "hives/itching due to hives." However, it is worth noting that it is extremely difficult to elicit a very specific answer (i.e. chronic hives/hives of an unknown source) from subjects in an open-ended question such as this. Other common (7%) incorrect mentions were "allergies" in general or hay fever allergies, a current known use of Claritin ®.

When presented with a list of correct and incorrect product use conditions, CIU sufferers demonstrated the strongest understanding of the 5 cohorts (71%). The other cohorts scored lower (38% to 49%). Overall, most of the subjects (92%) stated this product is intended for recurring or chronic hives of an unknown cause, but were not considered "correct/acceptable" because they also stated it is indicated for other incorrect conditions. Nearly one-quarter (22%) stated this product is intended for hay fever.

7.2.1.2 Scenarios

When presented with scenarios of various correct and incorrect product use scenarios, subjects demonstrated a stronger understanding of the uses of the product (66% - 99% correct/acceptable range across scenarios and cohorts).

Table E: Product Use

PRODUCT USE: Whether consumers understand the uses of Claritin®.							
Objectives	Question #	Tab Pg #	Cohorts- % Correct/ Acceptable				
			C1 CIU Suff.	C2 Gen. Pop.	C3 Low Lit.	C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg	C5 "Do not use" Acute Hives
			a	b	c	d	e
1a. Claritin® relieves and reduces itching and rash due to recurring or chronic hives of an unknown source (Chronic Idiopathic Urticaria). 1b. Claritin® should be only used after being previously told by a doctor that one has recurrent or chronic hives of an unknown source.	Direct Questions:						
	1.) Based on the label, what is this product used for? (open-end)	Pg.14	77 bcde	53	55	58	49
	2.) List of conditions that prod. is/is not intended to be used for?	Pg.47	71 bcde	41	48	49	38
	Scenarios: Correct and Incorrect Use						
	5/6.) Scenario Card B: Use on hives from allergic reaction to peanuts - tongue starting to swell/hard to swallow.	Pg.72	91 be	75	87b	88b	80
	7/8.) Scenario Card C: Use on rash from bee sting – trouble breathing.	Pg.85	96 bcde	85	87	88	86
	9/10.) Scenario Card D:Diagnosed w/CIU (correct use of product)	Pg.94	99 bcde	96	96	97	95
	11/12.) Scenario Card E: Use on red rash due to hiking in woods?	Pg.105	85 be	66	80b	80b	73
	15/16.) Scenario Card G: Use on first time break out of hives	Pg.118	90 bcde	73	80	82	75

7.2.2 Self-Selection

The purpose of the "self-selection" questions was to determine if consumers understood whether they could use Claritin® based on their personal history with hives, as well as their current medications and their medical condition.

Subjects who were CIU sufferers and did not have any of the label warnings were classified as "okay to use."

Subjects in any of the cohorts were classified as "ask a doctor first" if they had liver or kidney disease or were pregnant or nursing a child. ***Subjects in this classification did not have to have CIU*** because the self-selection question in this questionnaire version asked the subjects to assume they had been diagnosed by a doctor as having CIU.

Subjects were classified as "do not use" if they:

- Did not state they were currently experiencing hives or had experienced hives in the past 6 months, OR
- Stated they were experiencing hives or had experienced hives in the past 6 months, but they had never been told by a doctor that they have recurring or chronic hives with an unknown cause (CIU)

Results of the "self-selection" questions are provided in Table D below. Following are the key findings:

CIU Sufferers ("Okay to use")

- All of the CIU sufferers (100%) for whom drug use was appropriate (i.e., who were "okay to use the product") correctly self-selected the product for their use or stated they would ask their doctor prior to use.

Liver/Kidney Disease and Pregnant/Nursing ("Ask a doctor first")

- The majority (80%) of the subjects who should "ask a doctor before using" this product understood this warning and either correctly stated they would ask a doctor before using it or they did not select the product as one they could use.

Acute Hive Sufferers ("Do not use")

- More than half (54%) of the subjects who suffer from acute hives and should "not use the product" either correctly de-selected the product or stated they would "ask their doctor" prior to use. However, comprehension scores among this population improved (75%) for the direct scenario regarding use of the product for acute hives.
- Common reasons for incorrectly stating they could use the product were that the product "relieves/is for hives" (19%), followed by the product "relieves itching/rashes" (7%) and "I have allergies" (5%), a current known use of the product based on its brand name.

General Population & Low Literate Population ("Do not use" – not experience hives or acute hive sufferers)

- Almost three-fourths (70%) of the general population and more than two-thirds (65%) of the low literate population who were not appropriate candidates for Claritin® understood this and either correctly de-selected the product or stated they would "ask a doctor" prior to use.

Table F: Self-Selection

SELF-SELECTION: Whether consumers understand if they can personally use Claritin®.							
			Cohorts- % Correct/ Acceptable				
Objective	Question #	Tab Pg #	C1 CIU Suff. (OK to use)	C2 Gen. Pop. (Do not use)	C3 Low Lit. (Do not use)	C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg	C5 "Do not use" Acute Hives
Whether consumers understand if they can personally use Claritin®.	17/18/19/20.) Considering everything on the package label, is this product intended for you, personally, to take home and start using?	Pg.152	100	70	65	80	54

7.2.3 Warnings

7.2.3.1 General Warnings

Consumers across all cohorts demonstrated a strong understanding (75% - 96%) that this product should not be used in situations when serious symptoms are present. Notably, CIU sufferers demonstrated a particularly strong understanding of this (91% and 96%).

Table G: Warnings - General

WARNINGS: Whether consumers understand the warnings of Claritin®.							
Objective	Question #	Tab Page #	Cohorts- % Correct/ Acceptable				
			C1 CIU Suff.	C2 Gen. Pop.	C3 Low Lit.	C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg	C5 "Do not use" Acute Hives
			a	b	c	d	e
2a. Seek emergency medical attention if any of the following symptoms appear along with a rash, hives, or an insect	5/6.) Scenario Card B: Use on hives from allergic reaction to peanuts - tongue starting to swell/hard to swallow.	Pg.72	91 be	75	87b	88b	80
	7/8.) Scenario Card C: Use on rash from bee sting - trouble breathing.	Pg.85	96 bcde	85	87	88	86

7.2.3.2 Who can and cannot use Claritin®

Subjects demonstrated a strong understanding (75% - 99% correct/acceptable) of the scenarios that addressed situations with people who should and should not use the product (allergic to antihistamines, don't use unless diagnosed by a doctor with CIU, food allergies and bee stings).

Table H: Warnings - Who Can and Cannot Use the Product

WARNINGS: Consumers understand who can and cannot use Claritin®							
Objective	**Question #**	**Tab Page #**	**Cohorts- % Correct/ Acceptable**				
			C1 CIU Suff.	**C2 Gen. Pop.**	**C3 Low Lit.**	**C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg**	**C5 "Do not use" Acute Hives**
			a	b	c	d	e
3a. Do not use if you are allergic to Claritin® (Loratidine) or other antihistamines.	21/22.) Scenario Card I: Diagnosed with CIU - allergic to antihistamines.	Pg.169	98c	94	89	na	95
3b. Do not use for allergic skin reaction or hives unless you have been told by a doctor that you have CIU.	23.) Scenario Card J: Diagnosed with CIU – itchy rash similar to last episode (correct use of product).	Pg.172	99	97	99	na	98
3c. Do not use to treat food allergies or insect bites or stings.	5/6.) Scenario Card B: Use on hives from allergic reaction to peanuts - tongue starting to swell/hard to swallow.	Pg.72	91be	75	87b	88b	80
	7/8.) Scenario Card C: Use on rash from bee sting - trouble breathing.	Pg.85	96 bcde	85	87	88	86

7.2.3.3 Conditions one must first ask their doctor before using Claritin®

Subjects across all cohorts demonstrated a very strong understanding (94% - 100%) of all the conditions under which one must first ask a doctor before using Claritin®.

Table I: Warnings –Conditions One Must First Ask Doctor Before Using Claritin®

WARNINGS: Whether consumers understand under what conditions one must first ask their doctor before using Claritin®							
Objective	Question #	Tab Page #	Cohorts- % Correct/ Acceptable				
			C1 CIU Suff.	C2 Gen. Pop.	C3 Low Lit.	C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg	C5 "Do not use" Acute Hives
			a	b	c	d	e
4a. Ask a doctor before use if you have liver disease	24.) Scenario Card K: Diagnosed with CIU - has liver disease.	Pg.175	89	98a	97a	na	96a
4b. Ask a doctor before use if you have kidney disease	25.) Scenario Card L: Diagnosed with CIU - has kidney disease.	Pg.178	97	99	99	na	100
4c. Ask a doctor before use if you are pregnant or breast-feeding	28.) Scenario Card M: Diagnosed with CIU – pregnant.	Pg.186	99	99	100	na	100
4d. Do not give to children under 6 years of age unless directed by a doctor.	31/32.) Scenario Card P: Mother diagnosed with CIU – son is 11 and wants to use on him.	Pg.198	98	99e	99	na	94
	33/34.) Scenario Card Q: Daughter diagnosed with CIU – daughter is 5 years old.	Pg.202	99	99	100	na	98
	26/27.) Age of people who should not use	Pg.184	96	97	97	na	98

7.2.3.4 Conditions under which Claritin® should be used

Subjects in all cohorts clearly understood that if one's itching or rash has not improved after 5 days, one should ask a doctor (95% to 100%).

Table J: Warnings - Conditions Under Which Claritin® Should be Used

WARNINGS: Whether consumers understand the conditions under which Claritin® should be used.							
Objective	Question #	Tab Page #	Cohorts- % Correct/ Acceptable				
			C1 CIU Suff.	C2 Gen. Pop.	C3 Low Lit.	C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg	C5 "Do not use" Acute Hives
			a	b	c	d	e
5k. Ask a doctor if your itching or rash due to chronic or recurring hives do not improve after 5 days of treatment.	29.) Scenario Card N: Diagnosed with CIU – took product yesterday and still itches.	Pg.189	99b	95	99	na	99
	30.) Scenario Card O: Diagnosed with CIU – hives broke out 7 days ago – has been taking product every day – rash has not improved.	Pg.193	99	97	100	na	98

7.2.4 Directions

Overall, all subjects demonstrated a strong understanding of all the directions for use (67% - 100%). The low literate population scored lower (78%) then the others regarding one should not take more than one tablet in a 24 hour period.

Table K: Directions for Use

DIRECTIONS: Whether consumers understand the directions for use.							
Objective	Question #	Tab Page #	Cohorts- % Correct/ Acceptable				
			C1 CIU Suff.	C2 Gen. Pop.	C3 Low Lit.	C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg	C5 "Do not use" Acute Hives
			a	b	c	d	e
6a. Adults and children 6 years and over: 1 tablet every 24 hours.	35.) Number of tablets an adult 18 years of age or older should take at one time.	Pg.204	99 bcd	94	93	67	97d
	37.) Number of tablets a 10 year old child should take at one time.	Pg.206	99 bcde	95c	87	67	90
6b. Do not exceed 1 tablet in 24 hours.	36.) Scenario Card R: Diagnosed with CIU – took one tablet this a.m. – would like to take another for faster relief.	Pg.205	97 bce	93c	78	na	85
6c. Children under 6 years of age, ask a doctor	31/32.) Scenario Card P: Mother diagnosed with CIU – son is 11 and wants to use on him.	Pg.198	98	99e	99	na	94
	33/34.) Scenario Card Q: Daughter diagnosed with CIU – daughter is 5 years old.	Pg.202	99	99	100	na	98

7.3 *Label Comprehension – Package Insert*

After all of the questions addressing the package label were completed, subjects were shown the package insert and asked to read it. Again, subjects were told that after they read the package insert, they would be asked questions about it, but they would be able to refer to the insert as much as needed.

Subjects had a strong understanding that one cannot use Claritin® on acute hives (84% - 99% correct/acceptable) and of when to stop taking Claritin® after the itching stops (90% - 96% correct/acceptable). Comprehension was lower (57% - 81%) regarding the implications of taking more than one tablet within 24 hours, especially among the low literate (57%). Subjects appeared to have difficulty locating this statement as the most common reason for answering incorrectly was "don't know" (14% overall), followed by references to "would overdose" (3%).

Table L: Package Insert

PACKAGE INSERT							
Objective	Question #	Tab Page #	Cohorts- % Correct/ Acceptable				
			C1 CIU Suff.	C2 Gen. Pop.	C3 Low Lit.	C4 "Ask Dr. 1st": Liv/Kid/ Preg/Nsg	C5 "Do not use" Acute Hives
			a	b	c	d	e
1a. Do not use Claritin® for Acute Urticaria.	40/41.) Scenario Card S: Sometimes breaks out into hives as a result of job stress (acute hives).	Pg.219	86	84	94 abe	na	84
	42/43.) Scenario Card T: Begun to experience hives after being on Penicillin (acute hives).	Pg.229	91	92	97	na	92
	45/46.) Scenario Card U: Itchy rash from eating a cookie – lips and mouth swollen, throat tightening acute hives).	Pg.239	98b	91	99b	na	95
2b. Taking more than one tablet in 24 hours can cause drowsiness.	44.) What could happen if person takes more than 1 tablet within 24 hours (open-ended).	Pg.232	81c	78c	57	na	74c
2c. Stop taking Claritin® five days after the itching stops.	38/39.) About how long Claritin® should be taken after itching stops (open-ended).	Pg.210	96e	93	92	na	90

8.0 Appendix

8.1 Self-Recognition Data Listings

8.2 Tabulated Data

8.3 Protocol

8.4 Label

8.5 Questionnaires

8.5.1 Label Comprehension Questionnaire: Version A – Long Version

8.5.2 Label Comprehension Questionnaire: Version B – Short Version

8.5.3 Self-Administered Medical History

8.5.4 Medical History Review

8.5.5 Rash Photos – Q & M

8.5.6 Screening Questionnaires

8.5.6.1 Mall Intercept

8.5.6.2 Telephone Pre-Recruit – Cohort 1 (CIU)

8.5.6.3 Off-Site Low Literate – Cohort 3

8.5.6.4 Off-Site Liver or Kidney Disease – Cohort 4

8.5.7 REALM Test