# Phase 1 Seasonal Allergies FDA Online Study

# Survey Instrument

#### **SCREENING / INTRODUCTION**

Thank you for agreeing to participate in this study today. Make sure you are comfortable and can read the screen from where you sit. The survey will include some audio, so please make sure the sound is on and the speaker volume is turned up.

This study will take about 25 minutes to complete. We ask you to please complete the study in one sitting (without taking any breaks) in order to avoid distractions.

This study is about a new medicine. The study has three parts: First, we will ask you a few health-related questions. Next, we will let you explore a Web site about the new medicine. Finally, we will ask you some questions about the medicine.

#### S1. [Illness Diagnosis #1]

Have you ever been diagnosed by a health professional with any of the following conditions? (Check all that apply)

Arthritis
Sleep Apnea
Seasonal Allergies → [Continue]
Crohn's Disease
Diabetes
None of the above

# S2. [Illness Diagnosis #2]

In the past 12 months, have you suffered from seasonal allergies?

Yes → [Skip to Q-SA1] No → [Continue to S3]

# S3. [Illness Diagnosis #3]

Have you taken any medication for seasonal allergies in the past 12 months?

Yes → [Continue]
No → [Terminate]

The next few questions ask about seasonal allergies. The purpose of these questions is to find out what most people know and understand about seasonal allergies. Please answer the questions to the best of your ability. If you don't know the answer to a question, it is okay to check the box that says "Don't know".

# Q-SA1. [Seasonal Allergies Knowledge #1]

Which of the following is a common symptom of seasonal allergies?

- Sneezing
- Chronic pain in the ears and eyes
- Excessive thirst
- Blurry vision
- Don't know

## Q-SA2. [Seasonal Allergies Knowledge #2]

Which of the following is another name for seasonal allergies?

- Histamine
- Halitosis
- Hay fever
- Heat rash
- Don't know

# Q-SA3. [Seasonal Allergies Knowledge #3]

Seasonal allergies are often caused by your body's allergic response to:

- Parasites
- Petals
- Pollen
- Seeds
- Don't know

## Q-SA4. [Seasonal Allergies Knowledge #4]

What typically causes seasonal allergies in the fall?

- Orchard grass
- Bluegrass
- Pollinating trees
- Ragweed
- Don't know

On the next screen, you will see a Web site for a new product. The Web site will open in a new window. Please read the information on the site. You can take as much time as you want to review it.

The Web site has 5 pages. Feel free to explore the site, click on any links, and read the information as if you wanted to learn more about the new product. Once you finish reading, please click *Next* to move to the next part of the study.

Please make sure you have the speakers on your computer turned up so you can hear any audio.

## [DIRECT PARTICIPANTS TO APPROPRIATE WEB SITE]

## **SURVEY INSTRUCTIONS**

Please answer the following questions based on the Web site you visited.

## Q1. [Web Site Viewing]

Were you able to view and explore the Web site for GLISTELL?

Yes

No → [Terminate]

#### Q2. [Drug Knowledge (indication, illness)]

What condition does GLISTELL treat?

## Seasonal Allergies

**Indoor Allergies** 

**Bacterial Infections** 

**Upper Respiratory Infections** 

# Q3. [Embedded Visual Recall / Risk Info Exposure Proxy]

The Web site included a picture of the GLISTELL pill. What did that pill look like?

## The pill was green and oval

The pill was yellow and round The pill was orange and round The pill was brown and oval I did not see the pill

#### [PHASE 1: ASK Q8-11 BEFORE Q4-7]

Q8. [Risk Recall]

(0	pen ended)				
[DISPLAY	Q9 AND Q10 C	ON THE SAME SCI	REEN]		
When con	sidering a new	medicine, most	people ask two	questions:	
		e cause any side ide effects, how		side effects be?	
The questi	ions below ask	about these two	ideas.		
		elihood of Risk] people take GLIS	ΓELL, how many	will have any si	ide effects or negati
outcomes	? Please enter	a number in the	box below.		
people	e				
Q10. [Pero	ceived Risk - M	lagnitude of Risk	·]		
	oinionIf GLIST	TELL did cause a <sub>l</sub>	person to have	side effects or n	egative outcomes, l
1	2	3	4	5	6
Not at all					Very

serious

What are the side effects and negative outcomes of GLISTELL?

serious

Please check which of the following were mentioned on the Web site as warnings, side effects, or negative outcomes of taking GLISTELL. Even if you think a statement is true, please select it only if it was mentioned on the site.

[RANDOMIZE ORDER]	Mentione d on Web Site	Not Mentione d on Web Site
a. In rare cases, GLISTELL can cause a serious allergic reaction.	x	
b. GLISTELL should not be taken by young children (less than two years old) unless directed by a doctor.	х	
c. GLISTELL can make it difficult to concentrate.	x	
d. People with diabetes should not take GLISTELL.		х
e. People with high blood pressure should talk to their doctor before taking GLISTELL.	х	
f. A side effect of GLISTELL is nausea.		х
g. People with liver disease may need different doses of GLISTELL.		х
h. GLISTELL can cause drowsiness.		х

# Q4. [Benefit Recall]

What are the benefits of GLISTELL?

(open ended)

# [DISPLAY Q5 AND Q6 ON SAME SCREEN]

When considering a new medicine, most people ask two questions:

- (1) Will this medicine work?
- (2) If it does work, will it help a little or help a lot?

The questions below ask about these two ideas.

# Q5. [Perceived Efficacy - Likelihood of Benefit]

In your opinion...If 100 people take GLISTELL, for how many will the drug work? Please enter a number in the box below.

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pco	$\rho$ iC

## **Q6.** [Perceived Efficacy - Magnitude of Benefit]

In your opinionIf GLISTELL did help a person's seasonal allergy symptoms, how effective would GLISTELL be?									
1 2 3 Would eliminate very few symptoms	6 Id eliminate a	ll symptoms							
Q7. [Benefit Recall - Closed] [Benefit Knowledge]  Please check which of the following were mentioned on the Web site as benefits of taking									
GLISTELL. Even if you think a statement on the site.				•					
[RANDOMIZE ORDER]			Mentioned on Web Site	Not Mentioned on Web Site					
a. GLISTELL contains a long-acting antih	nistamine.		Х						
b. GLISTELL is taken once a day.			х						
c. GLISTELL treats seasonal allergy sym	ptoms.		х						
d. GLISTELL treats indoor allergy sympt	oms.			х					
e. GLISTELL works by boosting your boo	dy's immune sy	stem.		х					
f. GLISTELL contains a corticosteroid.				х					
g. GLISTELL treats symptoms such as na	asal congestion.		х						
h. GLISTELL treats symptoms such as bl	lurry vision.			х					
The next few questions ask about GLISTELL's risk and benefits. By risks, we mean the drug's possible side effects and negative outcomes. By benefits, we mean the drug's ability to improve symptoms of seasonal allergies.									
Q12. [Drug Balance of Risks / Benefits] Thinking about all its risks and benefits,	how would yo	u rate GLISTEL	L:						
1 2 3	4	5	6	7					
Risks outweigh benefits outweigh risks			Веі	nefits					

Please rate your agreement or disagreement with each of the following statements.

		Strongly	Somewhat	Neither	Somewhat	Strongly
		disagree	disagree	agree nor	agree	agree
	[RANDOMIZE ORDER]			disagree		
a.	The Web site clearly					
	communicated the					
	benefits of GLISTELL.					
b.	The Web site clearly					
	communicated the					
	risks of GLISTELL.					

# Q13. [Web Site Balance of Risks / Benefits]

Please think about how the risks and benefits of GLISTELL were presented on the Web site. Did the site place more emphasis on risks or more emphasis on benefits?

1	2	3	4	5	6	7
More emph	asis on risks			1	More emphasis	on
benefits						

# Q14. [Behavioral Intentions (seek drug info, talk to doc, etc.)]

**Based on what you learned, p**lease rate how likely or unlikely you are to do each of the following behaviors.

[RANDOMIZE ORDER]	Very Unlikely	Somewhat Unlikely	Neither Likely nor Unlikely	Somewhat Likely	Very Likely
a. Talk to your doctor about GLISTELL					
b. Ask your doctor about getting a sample of GLISTELL					
c. Ask your doctor to prescribe GLISTELL					
e. Join an online community or support group for people with seasonal allergies					
f. Join an online community or support group sponsored by GLISTELL					

# Q15. [Behavioral Intentions (seek drug info, talk to doc, etc.)]

**Based on what you learned, p**lease rate how likely or unlikely you are to do each of the following behaviors.

[RANDOMIZE ORDER]	Very Unlikely	Somewhat Unlikely	Neither Likely nor Unlikely	Somewhat Likely	Very Likely
a. Look for information online about other people's experience with GLISTELL					
b. Look for information <i>about</i> GLISTELL on medical Web sites					
c. Look for information about seasonal allergies on medical Web sites					
d. Print information from GLISTELL.com to discuss with your doctor					

# Q16. [Attitudes Toward Drug]

Based on what you learned, please rate GLISTELL. [RANDOMIZE ORDER OF ROWS]

	1	2	3	4	5	6	7	
Bad product								Good product
Disliked a lot								Liked a lot
Unpleasant								Pleasant
Poor quality								Good quality

# Q19. [Site Skepticism]

How likely or unlikely is it that the information about GLISTELL presented on this Web site is true?

1	2	3	4	5	6	7
Extren	nely					Extremely
Unlike	ly					Likely

#### Q20. [Site Skepticism]

How skeptical or not skeptical are you about the information about GLISTELL presented on this Web site?

1 2 3 4 5 6 7

Not at all Extremely Skeptical Skeptical

#### Q21. [Health Information Seeking - Source (HMTS)]

Have you looked for health or medical information from any of the following sources within the past 12 months? (Check all that apply)

#### **Offline Sources**

- Books, magazines, brochures, or other printed materials
- Family member, friend, or co-worker
- Health care provider
- Library or community center
- Telephone information number (1-800-Number)

#### **Online Sources**

- Search Engine (examples: Google, Bing)
- Health and medical Web site (examples: WebMd, MedlinePlus)
- Product Web site (example: Lipitor.com)
- Government organization Web site (example: National Institutes of Health)
- Non-profit organization Web site (examples: AARP, American Heart Assoc.)
- Commercial organization Web site (example: Merck, Novartis)
- Health insurance Web site (examples: Cigna, BlueCross and BlueShield)

-	Other:	_	 	 	 
			_		

- Did not look or go anywhere

## Q22. [Illness Information Seeking (Knowledge Proxy)]

In the past 12 months, how often did you use the Internet to look for health or medical information about seasonal allergies or treatments for seasonal allergies?

Once a week
Once a month
Every few months
Less often
Never

# Q23. [Mobile Phone or Device Ownership]

Do you own any of the following devices? (Check all that apply)

Mobile phone Smart phone or PDA (i.e., iPhone, Blackberry, Droid, iPod Touch) Tablet computer (i.e., iPad) None of the above

# Q24. [Web Navigation Skills]

We would like to know more about your Internet skills. For each statement below, please tell us to what extent you agree or disagree with the statement.

		-		_		
[Q24A.] I a	am extre	mely ski	lled at u	sing the	Web	
1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree
[Q24B.] I d	consider	myself k	knowled	geable a	bout	good search techniques on the Web.
1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree
[Q24C.] I I	know les	s about	using the	e Web tł	nan m	ost users.
1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree
[Q24D.] I l	know ho	w to find	d what I	am look	ing fo	r on the Web.
1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

## Q25. [Trust in Online Information (HMTS)]

**In general, how much do you or would you** trust information about prescription drugs from each of the following sources?

[RANDOMIZE ORDER]	Not at all	A little	Some	A lot
Drug Web sites (example:				
GLISTELL.com)				
Medical Web sites (example:				
WebMD.com)				
Online communities for people				
with seasonal allergies (example:				
Healthboards.com)				
Family and friends				
Doctors, nurses, and healthcare providers				
Food and Drug Administration (FDA)				
Pharmaceutical companies				
Prescription drug advertisements				

## **Q26.** [Current Prescription Drug Use]

Are you currently taking, or have you ever taken, any prescription drugs for seasonal allergies?

**Currently taking** 

Have taken in the past but not currently taking

Have never taken

## Q27. [History of Side Effects]

Have you ever had a SERIOUS side effect from a prescription drug?

- Yes
- No
- Don't Know

## **Q28.** [Time Since Diagnosis]

When did a healthcare professional first tell you that you had seasonal allergies?

- Six months ago or less
- More than six months ago but less than a year ago
- A year ago or more but less than 5 years
- Five years ago or longer

## Q29. [Severity of Illness - Subjective]

In general, how severe are your seasonal allergies? Would you describe them as:

- Very mild
- Mild
- Moderate
- Serious
- Severe

## Q31. [Health Literacy - Assistance (Leaflet Study)]

How often do you have someone (like a family member or friend) help you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- Never
- Occasionally
- Sometimes
- Often
- Always

# Q32. [Health Literacy - Self Efficacy (Leaflet Study)]

How confident are you filling out medical forms by yourself?

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Extremely

## Q33. [Survey Device]

What did you use to complete today's survey?

- Laptop computer / Netbook computer
- Desktop computer
- Handheld phone (iPhone, Blackberry, Droid)
- Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
- Other: \_\_\_\_\_

#### **CLOSING**

The purpose of this study is to learn about how individuals use information from medical Web sites. In order to get a real-life reaction, we used a pretend product in this study.

GLISTELL is not a real product and is not available for sale. Please see your healthcare provider for questions about seasonal allergies.

You have been very helpful. Thank you very much for your participation!