

**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

**WEB SITE INSTRUCTIONS**

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]**

**What are the side effects and negative outcomes of GLISTELL?**

(open ended)

**[DISPLAY Q9 AND Q10 ON THE SAME SCREEN]**

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

- (1) Will this medicine cause any side effects?
- (2) If it does cause side effects, how serious will the side effects be?

The questions below ask about these two ideas.

**Q9. [Perceived Risk - Likelihood of Risk]**

**In your opinion...If 100 people take GLISTELL, how many will have any side effects or negative outcomes? Please enter a number in the box below.**

\_\_\_ people

**Q10. [Perceived Risk - Magnitude of Risk]**

**In your opinion...If GLISTELL did cause a person to have side effects or negative outcomes, how serious would they be?**

1	2	3	4	5	6
Not at all serious					Very serious

**Q11. [Risk Recall - Closed]**

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.

<b>[RANDOMIZE ORDER]</b>	<b>Mentioned on Web Site</b>	<b>Not Mentioned on Web Site</b>
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.	x	
c. GLISTELL can make it difficult to concentrate.	x	
d. People with diabetes should not take GLISTELL.		x
e. People with high blood pressure should talk to their doctor before taking GLISTELL.	x	
f. A side effect of GLISTELL is nausea.		x
g. People with liver disease may need different doses of GLISTELL.		x
h. GLISTELL can cause drowsiness.		x

**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.**

\_\_\_ people

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

In your opinion...If GLISTELL did help a person's seasonal allergy symptoms, how effective would GLISTELL be?

1                      2                      3                      4                      5                      6  
 Would eliminate very few symptoms                      Would eliminate all 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 is true, please select it only if it was mentioned on the site.

<b>[RANDOMIZE ORDER]</b>	<b>Mentioned on Web Site</b>	<b>Not Mentioned on Web Site</b>
a. GLISTELL contains a long-acting antihistamine.	x	
b. GLISTELL is taken once a day.	x	
c. GLISTELL treats seasonal allergy symptoms.	x	
d. GLISTELL treats indoor allergy symptoms.		x
e. GLISTELL works by boosting your body's immune system.		x
f. GLISTELL contains a corticosteroid.		x
g. GLISTELL treats symptoms such as nasal congestion.	x	
h. GLISTELL treats symptoms such as blurry vision.		x

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 you rate GLISTELL:

1                      2                      3                      4                      5                      6                      7  
 Risks outweigh benefits                      Benefits  
 outweigh risks

**Q18. [Perceived Clarity / Understanding of Site]**







**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 am extremely skilled at using the Web.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24B.] I consider myself knowledgeable about good search techniques on the Web.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24C.] I know less about using the Web than most users.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24D.] I know how to find what I am looking for 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?

<b>[RANDOMIZE ORDER]</b>	<b>Not at all</b>	<b>A little</b>	<b>Some</b>	<b>A lot</b>
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!