

OMB Approval Number: 0910-XXXX  
OMB Expiration Date: XX/XX/XXXX

[See OMB Burden Statement on Page \[Insert Page Number\]](#)

**Gluten-Free Labeling of Food Products Experimental Study - y**  
**[Online](#) Participant Screener**

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Thank you for responding to the invitation to participate in the FDA research study on gluten-free statements on the food label. FDA is interested in knowing how consumers understand gluten-free statements and is recruiting for participation in an online questionnaire.

Would you mind answering a few questions to see if you are eligible to participate in the study? Please be assured that all of your answers are kept confidential and no personal identifying information is retained with your answers. Please feel free to skip any questions or discontinue this screener at any time.

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1. Are you at least 18 years old?
  - YES → (continue)
  - NO → [“You must be at least 18 years old to participate in this study. Thank you very much for your interest in our important research on gluten-free food labeling.”] (eliminate)

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**PUBLIC DISCLOSURE BURDEN STATEMENT**

Public reporting burden for this collection of information is estimated to average three (3) minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: “

Department of Health and Human Services  
Food and Drug Administration  
CFSAN/PRB Comments/HFS-24  
5100 Paint Branch Parkway  
College Park, MD 20740-3835.

2. Do you or does someone from your immediate family work for any of the following:
  - Market Research Firm → eliminate [“We are recruiting individuals with certain characteristics. Thank you very much for your interest in our important research on gluten-free food labeling.”]
  - The Food and Drug Administration, U.S. Department of Agriculture, or State or local food agency → eliminate [thank you statement]
  - Food Industry or Food Retailer → eliminate [thank you statement]
  - Gastroenterologist → eliminate [thank you statement]
  - Celiac Disease or Gluten intolerance Interest Groups or Association → eliminate [thank you statement]
  - Celiac Disease Research or Treatment Center → eliminate [thank you statement]
  
3. Have you shopped for groceries for yourself or others in the last month?
  - Yes → continue
  - No → eliminate [thank you statement]
  
4. Do you have medically diagnosed celiac disease or a gluten intolerance, or do you regularly purchase groceries or prepare food for someone with a medically diagnosed celiac disease or a gluten intolerance? Please choose the response that most closely matches your circumstances.
  - YES, I have medically diagnosed *celiac disease*
  - YES, I purchase groceries or prepare food for someone with medically diagnosed celiac disease
  - YES, I have medically diagnosed *gluten intolerance*
  - YES, I purchase groceries or prepare food for someone with medically diagnosed gluten intolerance
  - NO (retain only as needed for control group quotas. SKIP Q5.)
  
5. How was this diagnosis made? Please **read ALL** the options and then **choose just one**. Was the diagnosis made by:
  - Removing foods with gluten from your or the person’s diet (NOT APPROPRIATE FOR CELIAC DIAGNOSIS.)
  - Blood tests
  - Biopsy of the small intestine.

- Blood tests and a biopsy of the small intestine
  - None of the above. (retain only as needed for control group quotas)
  - Don't know (retain only as needed for control group quotas)
6. Do you, or does someone for whom you regularly prepare food or buy groceries, follow a gluten-free diet?
- YES
  - NO (retain only as needed for control group quotas)
7. Do you eat (or serve) *packaged, processed foods*?
- Yes → continue
  - No → eliminate [thank you statement]
8. When buying a food item for the first time, about how often would you say you read the food label, would you say you
- Never read the food label? → eliminate [thank you statement]
  - Sometimes read the food label ? → eliminate [thank you statement]
  - Often read the food label?
  - Always read the food label?

Office of Management and Budget (OMB) Burden Statement

We estimate the screener will take [three \(3\)](#) minutes to complete, including the time for reviewing instructions and answering questions. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

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[Food and Drug Administration](#)  
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