FDA Secondary and Comparative Claims and Biosimilars Disclosure Study

Recruitment email

[Any text in angle brackets "< >" indicates part of the script that will change based on the participant, or situation.]

Subject: Study about medication advertising
*Hi <**First Name**>*

You have an opportunity waiting!

Topic: Health products

Incentive: [IF CONSUMER] <$2.00 in e-Rewards(R) Currency>
                        [IF HEALTHCARE PROVIDER] <$30.00 honorarium>

Length: 20 minutes

LET'S BEGIN

We value your opinions!

– Your e-Rewards Team

Phase 1 Screener – Secondary and Comparative Claims

[DISPLAY]

Thank you for your interest in this research study. The purpose of the study is to learn more about prescription drug websites. First, we need to ask you a few screening questions to see if you are eligible to participate.

If you are eligible and agree to participate, you will look at a website for a new prescription drug and then answer some survey questions about what you saw. Viewing the website and completing the survey will take approximately **20 minutes**.

[--------------------------------------New screen--------------------------------------]

[Screener]

[SINGLE PUNCH]
S1. What year were you born?

___

[PROGRAMMER: S1 < 2002 SET EFLAG=0 'INELIGIBLE' – TERMINATE]

[--------------------------------------New screen--------------------------------------]

[SINGLE PUNCH]
S2. What is your gender?
1   Male
2   Female
3   Prefer not to answer

[--------------------------------------New screen--------------------------------------]

[SINGLE PUNCH]
S3. What is your current occupation?
1   Healthcare provider (e.g., physician, nurse, physician assistant)
2   Pharmaceutical company employee (e.g., pharma rep)
3   Market research employee/advertising employee

4   Employee of the Department of Health and Human Services
5   All other occupations

[PROGRAMMER: IF COHORT = 1 'Consumer' AND S3 !== 5 'All other occupations', SET EFLAG=0 'INELIGIBLE' – TERMINATE <u>after</u> S9; GO TO S4_C]
[PROGRAMMER: IF COHORT = 1 'HCP' AND S3 !== 1 'Healthcare provider', SET EFLAG=0 'INELIGIBLE' – TERMINATE <u>after</u> S9; GO TO S4_P]

[--------------------------------------New screen--------------------------------------]

[PROGRAMMER: DISPLAY S4_C THROUGH S6_C IF COHORT = 1 'Consumer']

[SINGLE PUNCH]
S4_C. Have you completed any formal training as a healthcare professional?

1   Yes
2   No
3   Not sure

[PROGRAMMER: IF COHORT = 1 'Consumer' AND S4_C = 1 'Yes' or 3 ("Not sure"), SET EFLAG=0 'INELIGIBLE' – TERMINATE <u>after</u> S9; GO TO S5_C]

[--------------------------------------New screen--------------------------------------]

[SINGLE PUNCH]
S5_C.   What is the highest level of school you have completed or the highest degree you have received?
        1   Less than high school
        2   High school graduate—high school diploma or the equivalent (for example: GED)

        3   Some college but no degree
        4   Associate degree in college
        5   Bachelor's degree (for example: BA, AB, BS)
        6   Advanced or postgraduate degree (for example: Master's degree, MD, DDS, JD, PhD, EdD)

[--------------------------------------New screen--------------------------------------]

[SINGLE PUNCH]
S6_C. What is your annual household income?
        1   Less than $30,000 per year
        2    $30,001 to $75,000 per year
        3    $75,001 to $150,000 per year
        4   More than $150,000 per year
        9   Prefer not to answer

[PROGRAMMER: IF COHORT = 1 'Consumer', SKIP S4_P THROUGH S7_P; GO TO S8]

[--------------------------------------New Screen--------------------------------------]

S4_P.   Which of the following best describes your profession?
1   Medical doctor/physician
2   Physician assistant
3   Nurse practitioner
4   Other

[-------------------------------------New screen-------------------------------------]

S5_P.   Do you consider yourself a primary care provider or specialist?
1   Primary care provider   ← [PCPs must select 1 to remain Eligible]
2   Specialist

[-------------------------------------New screen-------------------------------------]

S6_P.   Which of the following best describes your practice?
1   Family practice
2   General practice
3   Internal medicine
4   Other

[-------------------------------------New screen-------------------------------------]

S7_P. In a typical week, what percentage of your time is spent on direct patient care, such as seeing patients and reviewing their medical records? If you are not sure, please provide your best guess.
_____%   (Respondent has to indicate 50% or more to remain eligible)

[--------------------------------------New screen--------------------------------------]

[SINGLE PUNCH]
S8. Are you:
- 1   Hispanic or Latino
- 2   Not Hispanic or Latino
- 3   Prefer not to answer

[--------------------------------------New screen--------------------------------------]

[MULTIPLE PUNCH]
[PROGRAMMER: Multi-punch response items should be saved to dataset as binary variables with response options: 1='Selected' OR 0='Not selected'.**]**

S9. What is your race? *Select all that apply*.
- S9_1.   American Indian or Alaska Native
- S9_2.   Asian
- S9_3.   Black or African American
- S9_4.   Native Hawaiian or other Pacific Islander
- S9_5.   White
- S9_6.   Other
- S9_7.   Prefer not to answer   ←[If selected, no other options can be selected]

[PROGRAMMER: IF S9_7 = 1 'Selected', DISABLE OPTIONS S9_1 – S9_6]

[--------------------------------------New screen--------------------------------------]

[DISPLAY 'Thank and Terminate' IF EFLAG=0 'INELIGIBLE]

[Thank and Terminate]
We're sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible for this study. These reasons were decided earlier by the researchers. Thank you for your interest in this study and for taking the time to answer our questions today.

[IF EFLAG=0 'INELIGIBLE, END HERE]

[--------------------------------------New screen--------------------------------------]

You are eligible to participate in the study.

[---------------------------------------New screen---------------------------------------]

[SINGLE PUNCH]
Consent.   If you have read the previous screens and <u>agree</u> to participate, please click the Yes button. If

not, click the No button.

1   Yes, I <u>agree</u> to participate.   ←[Go to 'Randomization']

2   No, I <u>do not agree</u> to participate.   ←[End survey]

[PROGRAMMER: IF CONSENT = 1 'Yes', GO TO 'Randomization']

[PROGRAMMER: IF CONSENT !== 1 'Yes', SET EFLAG=0 'INELIGIBLE' – TERMINATE]

[---------------------------------------New screen---------------------------------------]

[Randomization]

[PROGRAMMER: Randomly assign participants to one of seven experimental conditions. Record assignment in variable XCONDITION with possible values shown in table below.

XCONDITION Value	XCONDITION Label
1	Comparative Claim present, Disclosure 1
2	Comparative Claim present, Disclosure 2
3	Comparative Claim present, Disclosure 3
4	Comparative Claim absent, Disclosure 1
5	Comparative Claim absent, Disclosure 2
6	Comparative Claim absent, Disclosure 3
7	Secondary claim only

[---------------------------------------New screen---------------------------------------]

Phase 2, Biosimilars Survey

[PROGRAMMING NOTE: Consent Screen 1 to be shown before the Screener]

[Consent Screen 1]

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.

[OMB Control #xxxxx Expires xxxxx]

[DISPLAY]

Thank you for your interest in this research study. The purpose of the study is to learn more about prescription drug promotions. First, we need to ask you a few screening questions to see if you are eligible to participate.

If you are eligible and agree to participate, you will look at an ad for a new prescription drug and then answer some survey questions about what you saw. Viewing the ad and completing the survey will take approximately **20 minutes**.

[-------------------------------------New screen-------------------------------------]

[Screener]

[SINGLE PUNCH]
S1. What year were you born?

_____

[PROGRAMMER: S1 < 2002 SET EFLAG=0 'INELIGIBLE' – TERMINATE]

[-------------------------------------New screen-------------------------------------]

[SINGLE PUNCH]
S2. What is your gender?
      1   Male
      2   Female
      3   Prefer not to answer

[-------------------------------------New screen-------------------------------------]

[SINGLE PUNCH]
S3. What is your current occupation?
      1   Healthcare provider (e.g., physician, nurse, physician assistant)
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      3   Market research employee/advertising employee
      4   Employee of the Department of Health and Human Services

5   All other occupations

[--------------------------------------New screen--------------------------------------]

[PROGRAMMER: DISPLAY S4_C THROUGH S6_C IF COHORT = 1 'Consumer']

[SINGLE PUNCH]
S4_C. Have you completed any formal training as a healthcare professional?

1   Yes
2   No
3   Not sure

[--------------------------------------New screen--------------------------------------]

[SINGLE PUNCH]
S5_C.   What is the highest level of school you have completed or the highest degree you have received?
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[--------------------------------------New screen--------------------------------------]

[SINGLE PUNCH]
S6_C. What is your annual household income?
1   Less than $30,000 per year
2   $30,001 to $75,000 per year
3   $75,001 to $150,000 per year
5   More than $150,000 per year
9   Prefer not to answer

[--------------------------------------New Screen--------------------------------------]

[SINGLE PUNCH]

S4_P.   Which of the following best describes your profession?

          1   Medical doctor/physician
          2   Physician assistant
          3   Nurse practitioner
          4   Other

[-------------------------------------New screen-------------------------------------]

[SINGLE PUNCH]

S5_P.   Do you consider yourself a primary care provider or specialist?

          1   Primary care provider   ← [PCPs must select 1 to remain Eligible]
          2   Specialist

[-------------------------------------New screen-------------------------------------]

[SINGLE PUNCH]

S6_P.   Which of the following best describes your practice?

          1   Family practice
          2   General practice
          3   Internal medicine
          4   Other

[-------------------------------------New screen-------------------------------------]

[NUMERICAL FIELD; SET RANGE 0 – 100]

S7_P. In a typical week, what percentage of your time is spent on direct patient care, such as seeing patients and reviewing their medical records? If you are not sure, please provide your best guess.

          _____%   (Respondent has to indicate 50% or more to remain eligible)

[------------------------------------New screen------------------------------------]

[SINGLE PUNCH]
S8. Are you:
      1   Hispanic or Latino
      2   Not Hispanic or Latino
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[MULTIPLE PUNCH]
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S9. What is your race? *Select all that apply*.
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      S9_3.   Black or African American
      S9_4.   Native Hawaiian or other Pacific Islander
      S9_5.   White
      S9_6.   Other
      S9_7.   Prefer not to answer   ←[If selected, no other options can be selected]

[PROGRAMMER: IF S9_7 = 1 'Selected', DISABLE OPTIONS S9_1 – S9_6]

[------------------------------------New screen------------------------------------]

[DISPLAY 'Thank and Terminate' IF EFLAG=0 'INELIGIBLE]

[Thank and Terminate]
We're sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible for this study. These reasons were decided earlier by the researchers. Thank you for your interest in this study and for taking the time to answer our questions today.

[IF EFLAG=0 'INELIGIBLE, END HERE]

[------------------------------------New screen------------------------------------]

You are eligible to participate in the study.

[DISPLAY CONSENT]

[------------------------------------New screen------------------------------------]

[SINGLE PUNCH]

Consent.　If you have read the previous screens and <u>agree</u> to participate, please click the Yes button. If not, click the No button.

1　Yes, I <u>agree</u> to participate.　　　←[Go to 'Randomization']

2　No, I <u>do not agree</u> to participate.　　←[End survey]

[PROGRAMMER: IF CONSENT = 1 'Yes', GO TO 'Randomization']

[PROGRAMMER: IF CONSENT !== 1 'Yes', SET EFLAG=0 'INELIGIBLE' – TERMINATE]

[--------------------------------------New screen--------------------------------------]

[Randomization]

[PROGRAMMER: Randomly assign participants to one of eight experimental conditions. Record assignment in variable XCONDITION with possible values shown in table below.

XCONDITION Value	XCONDITION Label
1	No Disclosure
2	Disclosure 1
3	Disclosure 2
4	Disclosure 3
5	Disclosure 4
6	Disclosure 5
7	Disclosure 6
8	Disclosure 7

[--------------------------------------New screen--------------------------------------]