**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

*=======================================================*

*Manage your account online.*

*Contact us if you have any issues.*

*Read our Member Agreement and Privacy Policy.*

*Unsubscribe from future e-Rewards emails. Please do not reply to this email.*

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**Phase 1 Screener – Secondary and Comparative Claims**

[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 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 after S9; GO TO S4\_C]**

**[PROGRAMMER: IF COHORT = 1 ‘HCP’ AND S3 !== 1 ‘Healthcare provider’, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after 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 after 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

1. 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----------------------------------------]**

**[PROGRAMMER: DISPLAY S4\_P THROUGH S7\_P IF COHORT = 2 ‘HCP’]**

**[SINGLE PUNCH]**

S4\_P. Which of the following best describes your profession?

1 Medical doctor/physician

2 Physician assistant

3 Nurse practitioner

4 Other

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND S4\_P = 4 ‘Other’, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; SKIP S5\_P through S7\_P, GO TO S8]**

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

**[PROGRAMMER: DISPLAY S5\_P IF S4\_P !== 1 ‘Other’]**

**[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

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND S5\_P !== 1 ‘Primary care provider’, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; GO TO S7\_P]**

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

**[PROGRAMMER: DISPLAY S6\_P IF S5\_P = 1 ‘Primary care provider’]**

**[SINGLE PUNCH]**

S6\_P. Which of the following best describes your practice?

1 Family practice

2 General practice

3 Internal medicine

4 Other

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND (S6\_P = 4 ‘Other’), SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; GO TO S7\_P]**

**[----------------------------------------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)

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND S7\_P < 50, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; GO TO S8]**

**[----------------------------------------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.

**[DISPLAY CONSENT]**

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

[SINGLE PUNCH]

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

1 Yes, I agree to participate. 🡨[Go to ‘Randomization’]

2 No, I do not agree 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)

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 after S9; GO TO S4\_C]**

**[PROGRAMMER: IF COHORT = 1 ‘HCP’ AND S3 !== 1 ‘Healthcare provider’, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after 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 after 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

1. 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----------------------------------------]**

**[PROGRAMMER: DISPLAY S4\_P THROUGH S7\_P IF COHORT = 2 ‘HCP’]**

**[SINGLE PUNCH]**

S4\_P. Which of the following best describes your profession?

1 Medical doctor/physician

2 Physician assistant

3 Nurse practitioner

4 Other

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND S4\_P = 4 ‘Other’, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; SKIP S5\_P through S7\_P, GO TO S8]**

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

**[PROGRAMMER: DISPLAY S5\_P IF S4\_P !== 1 ‘Other’]**

**[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

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND S5\_P !== 1 ‘Primary care provider’, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; GO TO S7\_P]**

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

**[PROGRAMMER: DISPLAY S6\_P IF S5\_P = 1 ‘Primary care provider’]**

**[SINGLE PUNCH]**

S6\_P. Which of the following best describes your practice?

1 Family practice

2 General practice

3 Internal medicine

4 Other

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND (S6\_P = 4 ‘Other’), SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; GO TO S7\_P]**

**[----------------------------------------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)

**[PROGRAMMER: IF COHORT = 2 ‘HCP’ AND S7\_P < 50, SET EFLAG=0 ‘INELIGIBLE’ – TERMINATE after S9; GO TO S8]**

**[----------------------------------------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.

**[DISPLAY CONSENT]**

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

[SINGLE PUNCH]

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

1 Yes, I agree to participate. 🡨[Go to ‘Randomization’]

2 No, I do not agree 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----------------------------------------]**