## Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites Screener (10/19/2022)

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, 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. The valid OMB control number for this information collection is 0910-087, and the expiration date is 05/31/2025. The time required to complete this information collection is estimated to average 5 minutes per response for the screener and 20 minutes for the survey, including the time for reviewing instructions and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov. This survey is being conducted on behalf of the U.S. Food and Drug Administration.

OMB control number: 0910-0872; Expiration: 05/31/2025

Thank you for your interest in this research study. The research involves looking at a website for a cancer treatment and completing an online questionnaire. First, we need to ask you a few screening questions to see if you are eligible to participate. Then, if you are eligible and agree to participate, you will be asked to view a website. After viewing the website, we will ask you to complete a survey. Viewing the website and completing the survey will take approximately 20 minutes.

## [PROGRAMMER: NEXT SCREEN]

S1. What is your age? \_\_\_\_\_ [IF <18, TERMINATE]

# [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

#### S2. What is your occupation?

- 1. Healthcare provider (e.g., physician, nurse, physical therapist) [TERMINATE]
- 2. Pharmaceutical employee (e.g., pharma rep) [TERMINATE]
- 3. Market research employee or advertising employee [TERMINATE]
- 4. Employee of the Department of Health and Human Services [TERMINATE]
- 5. None of the above [CONTINUE]

## [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

- S3. Have you ever been diagnosed with cancer by a doctor or other qualified health care provider?
  - 1. Yes [CONTINUE TO S4s]
  - 2. No [CONTINUE TO S4c]

# [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

# S4s. When was the first time that a doctor or other health care professional told you that you had cancer?

- 1. Less than six months ago
- 2. Between six months and less than two years ago
- 3. Between two years and less than five years ago
- 4. Between five years and less than ten years ago
- 5. More than ten years ago

# [PROGRAMMER: NEXT SCREEN]

## [SELECT ALL THAT APPLY]

#### S5s. What type of cancer(s) were you diagnosed with?

- Acute lymphocytic (or lymphoblastic) leukemia (ALL)
- Basal cell carcinoma [CONTINUE TO S4c]
- □ Bladder cancer
- □ Bone cancer
- Breast cancer
- □ Brain cancer
- □ Cervical cancer
- Chronic lymphocytic leukemia (CLL)
- Chronic myeloid leukemia (CML)
- □ Colon & rectal
- □ Endometrial cancer
- □ Kaposi's sarcoma
- □ Kidney cancer
- Leukemia, includes Acute myeloid leukemia (AML)
- □ Lip & oral cancer
- □ Liver cancer
- □ Lung cancer
- Lymphoma, includes non-Hodgkin lymphoma, Hodgkin lymphoma Multiple myeloma
- □ Melanoma
- □ Merkel cell carcinoma [CONTINUE TO S4c]
- □ Mesothelioma
- □ Non-small cell lung cancer
- Nonmelanoma skin cancer [CONTINUE TO S4c]
- □ Oral cancer
- Ovarian cancer
- □ Pancreatic cancer
- □ Prostate cancer

- □ Sarcoma
- Skin cancer [CONTINUE TO S4c]
- □ Small cell lung cancer
- Squamous cell carcinoma [CONTINUE TO S4c]
- □ Thyroid Cancer
- □ Other

#### [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

S6s. Are you currently in active treatment for your cancer? Active treatment could include surgery, radiation, or receiving medication like chemotherapy, immunotherapy, or hormone therapy.

1. Yes [TERMINATE]

2. No [CONTINUE]

## [PROGRAMMER: NEXT SCREEN] [SELECT ALL THAT APPLY]

**S7s. What type(s) of cancer treatment have you received for your cancer**? *Select all that apply* 

□ Surgery

## □ Radiation

- □ Chemotherapy (pills or infusions)
- □ Immunotherapy, hormone therapy, or targeted therapy
- □ Stem cell or bone marrow transplant
- □ Other cancer treatments (specify) [text box]
- □ I have not received any medical treatment for cancer [CONTINUE TO S4c]

## [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

S4c. Have you ever provided care for or made health care decisions for someone with cancer?

- 1. Yes [CONTINUE]
- 2. No [TERMINATE]

[PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

# S5c. Was any of this care provided as part of a job (for example, as a nurse or professional home health aide)?

1. Yes [TERMINATE]

2. No [CONTINUE]

[PROGRAMMER: NEXT SCREEN] [SELECT ALL THAT APPLY]

## S6c. Thinking about the person you provided care for, what type of cancer(s) did they have?

- Acute lymphocytic (or lymphoblastic) leukemia (ALL)
- Basal cell carcinoma [TERMINATE]
- □ Bladder cancer
- Bone cancer
- □ Breast cancer
- □ Brain cancer
- □ Cervical cancer
- Chronic lymphocytic leukemia (CLL)
- Chronic myeloid leukemia (CML)
- □ Colon & rectal
- Endometrial cancer
- □ Kaposi's sarcoma
- □ Kidney cancer
- Leukemia, includes Acute myeloid leukemia (AML)
- □ Lip & oral cancer
- □ Liver cancer
- □ Lung cancer
- □ Lymphoma, includes non-Hodgkin lymphoma, Hodgkin lymphoma Multiple myeloma
- Melanoma
- □ Merkel cell carcinoma [TERMINATE]
- Mesothelioma
- □ Non-small cell lung cancer
- □ Nonmelanoma skin cancer [TERMINATE]
- Oral cancer
- Ovarian cancer
- □ Pancreatic cancer
- Prostate cancer
- □ Sarcoma
- Skin cancer [TERMINATE]
- □ Small cell lung cancer
- □ Squamous cell carcinoma [TERMINATE]

Thyroid CancerOther

[Note: the distribution of S6c to be examined in the pretest to determine the feasibility of including quotas in main study]

[PROGRAMMER: NEXT SCREEN] [SELECT ALL THAT APPLY]

S7c. Thinking about the person you provided care for, what type(s) of cancer treatment have they received for their cancer? Select all that apply

- □ Surgery
- □ Radiation
- □ Chemotherapy (pills or infusions)
- □ Immunotherapy, hormone therapy, or targeted therapy
- □ Stem cell or bone marrow transplant
- Other cancer treatments (specify) [text box]
- They have not received any medical treatment for cancer [TERMINATE]
- □ I don't know what type of cancer treatment they received [TERMINATE]

# [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

#### S8. What is your sex?

- 1. Male
- 2. Female
- 3. Prefer not to answer

## [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

#### S9. Are you Hispanic or Latino?

- 1. Yes
- 2. No
- 3. Prefer not to answer

[PROGRAMMER: NEXT SCREEN] [SELECT ALL THAT APPLY]

#### S10. What is your race? (You may select one or more races.)

- 1. American Indian or Alaska Native
- 2. Asian
- 3. Black or African American
- 4. Native Hawaiian or other Pacific Islander
- 5. White
- 6. Prefer not to answer

# [PROGRAMMER: NEXT SCREEN] [SINGLE PUNCH]

#### S11. 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. Vocational or Technical School degree
- 5. Associate's degree
- 6. Bachelor's degree (for example: BA, AB, BS)
- 7. Some postgraduate work but no degree
- 8. Advanced or post-graduate degree (for example: Master's degree, MD, DDS, JD, PhD, EdD)

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

#### [PROGRAMMER: NEXT SCREEN]

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. However, thank you for your interest in this study and for taking the time to answer our questions today.

[TERMINATE IF EFLAG=0 'INELIGIBLE'] [IF EFLAG=1 'ELIGIBLE'; CONTINUE, RANDOMLY ASSIGN PARTICIPANTS TO A STUDY CONDITION]

[PROGRAMMER: NEXT SCREEN]

You are eligible to participate in the study.