

APPENDIX B

Screener

[Placeholder for OMB statement]

FDA Prescriber Survey to Assess Boxed Warnings Perceptions

Screener with Programming Notes

PROGRAMMER:

- Program progresses through the questioning in a “one-way” manner; participants should not be able to return to questions after they have answered them.
- Responses to all questions are voluntary; if the respondent does not answer a question, the respondent should stay on the same page and be shown the “MISSING ANSWER(S)” validation, after which they should be allowed to move to the next page. If any of the screener questions are missing after validations, please terminate.
- Include one additional variable in the dataset not shown in this document: **Respondent_ID** (a unique identifier).
- If ineligible, please show the “THANK AND TERMINATE” message on new screen:
“Thank you for your time. You do not qualify to participate in the current study. Please continue to check for opportunities to participate in research through Survey Healthcare.”
- There will be two separate study surveys, one for the Vagifem prescribing scenario and one for the Direct Acting Antivirals (DAA) prescribing scenario. Specialists will be assigned to the appropriate survey for their specialty, while general practitioners (GP) may qualify for one or both, depending on their experience treating the medical condition. GPs who qualify for both will be randomized to either survey.

[INTRO TEXT]

Thank you for your interest in this survey. To get started, we first need to ask you a few questions to see if you are eligible to take the longer survey. By participating in this pre-survey, you are consenting to your information being used for the purposes of this research study. This information will be kept whether or not you qualify to continue to the study.

May we continue?

Yes
No

Thank you for your interest in participating in this survey to help the United States Food and Drug Administration (FDA) better understand how healthcare professionals make prescribing decisions. Please make sure to answer all of the following questions during this initial screening process to determine if you are eligible to participate in this study.

Prescriber. Are you a healthcare professional with prescribing authority?
[SINGLE PUNCH]

| | |
|----------------------------------|----|
| Yes, I am a physician. | 01 |
| Yes, I am a nurse practitioner. | 02 |
| Yes, I am a physician assistant. | 03 |
| No | 04 |

[IF **Prescriber** = 04 (“No”), THEN INELIGIBLE. THANK AND TERMINATE.]

[NEW SCREEN]

Area. Which best describes your medical specialty?
[SINGLE PUNCH]

| | |
|---------------------------|----|
| Emergency medicine | 01 |
| Endocrinology | 02 |
| Family medicine | 03 |
| General medicine | 04 |
| Internal medicine | 05 |
| Gastroenterology | 06 |
| Hepatology | 07 |
| Infectious disease | 08 |
| Obstetrics and gynecology | 09 |
| Pediatric medicine | 10 |
| Geriatric medicine | 11 |
| Psychiatry | 12 |
| Other | 13 |

[IF **Area** = 01 (“Emergency medicine”), 02 (“Endocrinology”), 10 (“Pediatric medicine”), 12 (“Psychiatry”), or 13 (“Other”), THEN INELIGIBLE. THANK AND TERMINATE.]

[IF **Prescriber** = 02 (“Nurse practitioner”), or 03 (“Physician assistant”) AND **Area** does not = 03 (“Family medicine”), 04 (“General medicine”), 05

(“Internal medicine”), 09 (“Obstetrics and gynecology”), or 11 (“Geriatric medicine”) THEN INELIGIBLE. THANK AND TERMINATE.]

[QUOTA FOR **AREA**, BASED ON MAIN SURVEY COMPLETES]

| Category | Subgroup | Quota |
|-----------------------|---|-------|
| General practitioners | Family medicine, General medicine, and Internal medicine | 694 |
| Specialists | OB/GYNs or Geriatricians | 231 |
| | Infectious Disease Specialists or Gastroenterologists/Hepatologists | 231 |

[NEW SCREEN]

Activity. What do you consider as your major professional activity?

[SINGLE PUNCH]

- Office-based practice 01
- Hospital-based practice 02
- Resident 03
- Medical teaching 04
- Medical research 05
- Administration 06
- Other 07

[IF **Activity** = 03 (“Resident”), 04 (“Medical teaching”), 05 (“Medical research”), 06 (“Administration”), or 07 (“Other”), THEN INELIGIBLE. THANK AND TERMINATE.]

[NEW SCREEN]

TimePtCare. About how much time do you spend on direct patient care?

[SINGLE PUNCH]

- Less than 20% 01
- 20-50% 02

51-70%

03

More than 70%

04

[IF **TimePtCare** = 01 (Less than 20%), THEN INELIGIBLE. THANK AND TERMINATE.]

[IF **Area** = 03 (Family medicine), 04 (General medicine), or 07 (Internal medicine) AND **TimePtCare** < 03 (50-70%), THEN INELIGIBLE. THANK AND TERMINATE.]

[NEW SCREEN]

RxVolume. Over the course of a week, about how many prescriptions do you write?

[SINGLE PUNCH]

| | | |
|------------------------|----|----|
| Less than 30 per week | 01 | |
| 30 to 79 per week | | 02 |
| 80 to 119 per week | | 03 |
| More than 120 per week | | 04 |

[IF **RxVolume** = 01 (“Less than 30 per week”), THEN INELIGIBLE. THANK AND TERMINATE.]

[NEW SCREEN]

CdnFamiliarity. Please indicate whether you have treated each of the following clinical conditions in the last 30 days.

[MULTIPLE PUNCH, options are Yes/No]

[IF **Area** = 03 (Family medicine), 04 (General medicine), or 05 (Internal medicine) AND **CdnFamiliarity** = 1 (“Yes”) for both 05 (“Postmenopausal Atrophic Vaginitis/Vulvovaginal Atrophy” AND 06 (“Chronic Hepatitis”), THEN randomize to either Vagifem survey or DAA survey]

[IF **Area** = 03 (Family medicine), 04 (General medicine), or 05 (Internal medicine) AND **CdnFamiliarity** = 1 (“Yes”) for 05 (“Postmenopausal Atrophic Vaginitis/Vulvovaginal Atrophy” AND **CdnFamiliarity** = 0 (“No”) for 06 (“Chronic Hepatitis”) THEN assign to Vagifem survey]

[IF **Area** = 03 (Family medicine), 04 (General medicine), or 05 (Internal medicine) AND **CdnFamiliarity** = 1 (“Yes”) for 06 (“Chronic Hepatitis”) AND **CdnFamiliarity** = 0 (“No”) for 05 (“Postmenopausal Atrophic Vaginitis/Vulvovaginal Atrophy”, THEN assign to DAA survey]

[IF **Area** = 09 (“Obstetrics and Gynecology”) or 11 (“Geriatric medicine”) THEN assign to Vagifem survey]

[IF **Area** = 06 (“Gastroenterology”), 07 (“Hepatology”), or 08 (“Infectious disease”), THEN assign to DAA survey]

| | | |
|-----------------------------|----|----|
| Asthma | 01 | |
| HIV Infection | | 02 |
| Inflammatory Bowel Diseases | 03 | |

| | | |
|--|----|----|
| Osteoporosis | 04 | |
| Postmenopausal Atrophic Vaginitis/Vulvovaginal Atrophy | | 05 |
| Chronic Hepatitis C Viral Infection | 06 | |

[NEW SCREEN]

Age. What is your age?
[OPEN-ENDED NUMERICAL]

years old

PracticeYears. Approximately how many years have you been practicing medicine?
[OPEN-ENDED NUMERICAL]

years

[NEW SCREEN]

Hispanic. Are you Hispanic, Latino/a, or of Spanish origin?
[SINGLE PUNCH]

Yes, of Hispanic, Latino/a, or Spanish origin 01
No, not of Hispanic, Latino/a, or Spanish origin 02

Race. Which of the following best describes your race? Mark one or more.
[MULTIPLE PUNCH]

| | | NO | YES |
|----------------|---|----|-----|
| Race_1. | American Indian or Alaska Native | 00 | 01 |
| Race_2. | Asian | 00 | 01 |
| Race_3. | Black or African American | 00 | 01 |
| Race_4. | Native Hawaiian or Other Pacific Islander | 00 | 01 |
| Race_5. | White | 00 | 01 |

[NEW SCREEN]

Gender. What is your gender?
[SINGLE PUNCH]

Male 01

| | | |
|----------------------|----|----|
| Female | 02 | |
| Prefer not to answer | | 03 |

[NEW SCREEN]

Location. In what kind of location is your practice?
[SINGLE PUNCH]

| | | |
|----------|----|----|
| Urban | | 01 |
| Suburban | 02 | |
| Rural | 03 | |

[IF INELIGIBLE DISPLAY (THANK AND TERMINATE)]

Thank you for your time. You do not qualify to participate in the current study. Please continue to check for opportunities to participate in research.

[DISPLAY IF ELIGIBLE]

You are eligible to participate in the current study. Please click the button below to read through our consent form and then proceed to the survey.

[CONTINUE TO CONSENT FORM]

[IF Area = 03 (“Family medicine”), 04 (“General medicine”), 05 (“Internal medicine”), THEN CONTINUE TO CONSENT FORM FOR GENERAL PRACTITIONERS]

[IF Area = 06 (“Gastroenterology”), 07 (“Hepatology”), 08 (“Infectious disease”), THEN CONTINUE TO CONSENT FORM FOR DAA SPECIALISTS]

[IF Area = 09 (“Obstetrics and gynecology”) or 11 (“Geriatric medicine”) THEN CONTINUE TO CONSENT FORM FOR VAGIFEM SPECIALISTS]