

APPENDIX C

Healthcare Provider Perception of Boxed Warning Information Survey
Survey Questionnaire: Vulvar and Vaginal Atrophy Scenario
Version: 10/23/20

Prescriber Survey to Assess Boxed Warnings Perceptions

Survey Questionnaire: Vulvar and Vaginal Atrophy

(Questions used for pre-testing condition are included at the end)

Introductory Script:

Thank you for your participation in this survey. The first few questions will focus on the condition of vulvar and vaginal atrophy in menopause, which you may also know as postmenopausal atrophic vaginitis.

//PROGRAMMING NOTES: Display each question on its own separate screen. Do not allow participants to go back on any screen. Include soft prompts for all items. //

Question Type: Single Punch

Question Q1

Variable Name: Q1

Variable Label: Q1 Familiarity with treating VVA

Question Text: How experienced are you with treating vulvar and vaginal atrophy?

Value	Value Label
1	Not at all experienced
2	Slightly experienced
3	Somewhat experienced
4	Experienced
5	Very experienced
--99	Refused

Question Type: Single Punch

Question 2

Variable Name: Q2

Variable Label: Q2 Number of patients typically seen

Question Text: How many patients do you typically see for treatment of vulvar and vaginal atrophy?

Value	Value Label
1	One to two patients a week, or fewer
2	Several patients a week
3	Several patients a day
98	Unsure/Don't know
--99	Refused

Question Type: Single Punch

Question Q3

Variable Name: Q3

Variable Label: Q3 Bothersomeness of symptoms

Question Text: In general, how bothersome are symptoms of vulvar and vaginal atrophy reported by most of your patients who have the condition?

Value	Value Label
1	Not at all bothersome
2	Slightly bothersome
3	Somewhat bothersome
4	Bothersome
5	Very bothersome
98	Unsure/Don't know
--99	Refused

Question Type: Single Punch

Question Q4A

Variable Name: Q4A

Variable Label: Q4A Experience prescribing vaginal inserts

Question Text: Which of the following is true of your prescribing vaginal inserts (e.g., Vagifem, Imvexxy) for the treatment of vulvar and vaginal atrophy?

Value	Value Label
1	I have written new prescriptions for this product
2	I have only prescribed a refill for this product
3	I have never prescribed this product
98	Unsure/don't know

-99	Refused
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// PROGRAMMING NOTE: SKIP 4B if 4A = 2, 3, 4, or 98//

Question Type: Single Punch

Question Q4B

Variable Name: *Q4B*

Variable Label: Q4B Frequency of prescribing vaginal inserts

Question Text: On average, how often do you prescribe vaginal inserts (e.g., Vagifem, Imvexxy) for the treatment of vulvar and vaginal atrophy?

Value	Value Label
1	I prescribe this product one or more times a week
2	I prescribe this product a few times a month
3	I prescribe this product a few times a year
98	Unsure/Don't know
-99	Refused

Question Type: Multi-Punch

Question Q5

Variable Name: *Q5*

Variable Label: Q5 Which treatments recommend or prescribe in a month

Question Text: Which of the following other treatments would you recommend or prescribe in a typical month? (Select all that apply.)

Value	Value Label	Variable Label
Q5_1	Over-the-counter products (e.g., personal lubricant)	Q5_1 Typical treatment: OTC products
Q5_2	Vaginal estrogen rings (e.g., Estring, Femring)	Q5_2 Typical treatment: Estrogen rings
Q5_3	Vaginal estrogen creams (e.g., Premarin, Estrace)	Q5_3 Typical treatment: Estrogen creams
Q5_4	Topical estrogen gels (e.g., Estrogel, Divigel)	Q5_4 Typical treatment: Estrogen gels
Q5_5	Oral estrogens (e.g., Premarin)	Q5_5 Typical treatment: Oral estrogens
Q5_6	Estrogen transdermal patches (e.g., Alora, Estraderm)	Q5_6 Typical treatment: Estrogen patch
Q5_7	Other prescription product that does not contain estrogen	Q5_7 Typical treatment: Other prescription product w/o estrogen
Q5_8	Other (specify)	Q5_8 Typical treatment: Other

Value	Value Label
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1	Selected
0	Not selected

For the next few questions, we would like you to consider your patients who are postmenopausal women with vulvar and vaginal atrophy and are complaining of symptoms such as vaginal itching and discomfort or pain during intercourse. They have previously tried over-the-counter ointments with little success.

// PROGRAMMING NOTE: [SHOW SCENARIO AT THE TOP OF THE SCREEN FOR QUESTION 6]//

Question Type: Single Punch

Question Q6

Variable Name: Q6

Variable Label: Q6 Likelihood of discussing inserts

Question Text: How likely are you to discuss vaginal inserts, such as Vagifem or Imvexxy, as a potential option for these patients?

Value	Value Label
1	Very unlikely
2	Unlikely
3	Somewhat likely
4	Likely
5	Very likely
-99	Refused

Question Type: Single Punch

Question Q7

Variable Name: Q7

Variable Label: Q7 Risk assessment of vaginal inserts

Question Text: Which of the following statements describe your assessment of the safety of vaginal inserts used to treat vulvar and vaginal atrophy?

Value	Value Label
1	Risks are minimal for almost all patients
2	Risks are minimal for most patients, but are significant for some patients
3	Risks are significant for most patients
4	I am not familiar enough with vaginal inserts to make an assessment
-99	Refused

Question Type: Single Punch

Question Q8A

Variable Name: Q8A

Variable Label: Q8A Assessment of inserts vs. oral estrogen

Question Text: Which statement best describes your assessment of the safety of vaginal inserts compared to oral estrogen products?

Value	Value Label
1	Vaginal inserts are safer than oral estrogen products
2	Vaginal inserts are less safe than oral estrogen products
3	Vaginal inserts are no more and no less safe than oral estrogen products
4	The safety of vaginal inserts versus oral estrogen products has not been established
5	I am not familiar enough with vaginal inserts to make an assessment
-99	Refused

Question Type: Single Punch

Question Q8B

Variable Name: Q8B

Variable Label: Q8B Assessment of inserts vs. transdermal estrogen

Question Text: Which statement best describes your assessment of the safety of vaginal inserts compared to transdermal estrogen products?

Value	Value Label
1	Vaginal inserts are safer than transdermal estrogen products
2	Vaginal inserts are less safe than transdermal estrogen products
3	Vaginal inserts are no more and no less safe than transdermal estrogen products
4	The safety of vaginal inserts versus transdermal estrogen products has not been established
5	I am not familiar enough with vaginal inserts to make an assessment
-99	Refused

Question Type: Single Punch

Question Q8C

Variable Name: Q8C

Variable Label: Q8C Benefits/risks of inserts

Question Text: Which statement best describes your general perspective on the benefits versus risks of vaginal inserts for patients with vulvar and vaginal atrophy.

Value	Value Label
1	The benefits of vaginal inserts outweigh the risks for most patients
2	The benefits of vaginal inserts outweigh the risks for some, but not most, patients
3	The benefits of vaginal inserts outweigh the risks for very few patients
4	I am not familiar enough with vaginal inserts to make an assessment
-99	Refused

Question Type: Multi-Punch

Question Q9

Variable Name: Q9

Variable Label: Q9 Factors most important when choosing to prescribe vaginal inserts

Question Text: Which of the following factors play the most important role when deciding whether or not to prescribe vaginal inserts to a patient with vulvar and vaginal atrophy? Please choose the three factors that you consider to be most important.

//PROGRAMMING NOTE: ALLOW PARTICIPANTS TO SELECT UP TO THREE ANSWERS//

[RANDOM ORDER EXCEPT FOR OTHER] [//Multi-punch//]

Variable Name	Variable Text	Variable Label
Q9_1	Considerations of this patient's ability to use the product as prescribed	Q9_1 Factor: Patient ability to use
Q9_2	This patient's understanding of and comfort with the risks of this medication	Q9_2 Factor: Understanding and comfort with risks
Q9_3	This patient's previous experience with treatments (over-the-counter and prescription)	Q9_3 Factor: Patient's previous experience
Q9_4	This patient's medical and health context (e.g., medical history, comorbidities, family history)	Q9_4 Factor: Medical and health context
Q9_5	Considerations of this patient's access to the product (e.g., cost, insurance)	Q9_5 Factor: Patient access
Q9_6	Extent, duration, and severity of this	Q9_6 Factor: Symptoms

	patient's symptoms	
Q9_7	Patient's preference for a mode of administration	Q9_7 Factor: Patient preference for administration
Q9_8	Potential duration of treatment use/course	Q9_8 Factor: Duration
Q9_9	Other (please specify)	Q9_9 Factor: Other

Value	Value Label
1	Selected
0	Not selected

Question Type: Multi-Punch

Question Q10

Variable Name: Q10

Variable Label: Q10 Top three questions from patients about using vaginal inserts

Question Text: What are the top three comments or questions you have you heard from patients about using vaginal inserts to treat vulvar and vaginal atrophy?

(Select up to three.)

//PROGRAMMING NOTE: ALLOW PARTICIPANTS TO SELECT UP TO THREE ANSWERS//

[//Multi-punch//]

Variable Name	Variable Text	Variable Label
Q10_1	Pros about vaginal inserts' application method	Q10_1 Pros application method
Q10_2	Hearing positive things about how well vaginal inserts work	Q10_2 Heard positive things
Q10_3	Whether vaginal inserts may be safer than other estrogen treatments	Q10_3 Inserts safer than other estrogen
Q10_4	A desire to try something new	Q10_4 Try something new
Q10_5	Cons about vaginal inserts' application method	Q10_5 Cons application method
Q10_6	Concerns about insurance coverage or cost	Q10_6 Insurance coverage/cost
Q10_7	Hearing negative things about how well vaginal inserts work	Q10_7 Hearing negative things
Q10_8	Concerns about using an estrogen treatment	Q10_8 General concerns re: estrogen
Q10_9	Other (specify)	Q10_9 Other

Value	Value Label
1	Selected
0	Not selected

Question Type: Multi-Punch

Question Q11

Variable Name: *Q11*

Variable Label: Q11 Top three topics talk to patients about vaginal inserts

Question Text: What are the top three topics that you prioritize when talking to your patients about vaginal inserts as a treatment option?

//PROGRAMMING NOTE: ALLOW PARTICIPANT TO SELECT UP TO THREE ANSWERS//

[RANDOM ORDER EXCEPT FOR LAST OPTION] [//Multi-punch//]

Variable Name	Variable Text	Variable Label
Q11_1	How the product works	Q11_1 Talking top 3: How product works
Q11_2	Expected benefits of the product	Q11_2 Talking top 3: Expected benefits
Q11_3	Common side effects of the product	Q11_3 Talking top 3: Common side effects
Q11_4	Rare but serious side effects of the product	Q11_4 Talking top 3: Rare serious effects
Q11_5	Patient's medical history (e.g., personal history or family history, possible co-morbidities)	Q11_5 Talking top 3: Medical history
Q11_6	The importance of using the product as directed	Q11_6 Talking top 3: Importance of use as directed
Q11_7	Other (Specify)	Q11_7 Talking top 3: Other

Value	Value Label
1	Selected
0	Not selected

//PROGRAMMING NOTE: If Q11D selected, display Q11_RISKS. OTHERWISE, PROCEED TO Q12 //

Question Type: Open End Essay

Question 11_RISKS

Variable Name: *Q11_RISKS*

Variable Label: Q11_RISKS Side effects discussed

Question Text: You said that you discuss rare but serious side effects of the product. What potential side effects do you discuss?

Question Type: Multi-Punch

Question Q12

Variable Name: Q12

Variable Label: Q12 How monitor for safety risks and side effects after prescribing vaginal inserts

Question Text: How do you most commonly monitor your patients for potential safety risks and side effects after prescribing vaginal inserts for vulvar and vaginal atrophy? Select all that apply.

Variable Name	Value	Variable Label
Q12_1	I schedule routine follow-up appointments with patients.	Q12_1 Monitor: Follow-up appointment
Q12_2	I instruct patients to get bloodwork before follow-up appointment.	Q12_2: Monitor: Bloodwork
Q12_3	I instruct patients to call and schedule an appointment if they experience side effects.	Q12_3 Monitor: Appointment if side effects
Q12_4	I leave it to the patient to follow up if they feel a need to.	Q12_4 Monitor: Leave up to patient
Q12_5	A follow-up appointment is not necessary.	Q12_5 Monitor: Follow-up not necessary
Q12_6	Other (specify)	Q12_6 Monitor: Other

Value	Value Label
1	Selected
0	Not selected

Question Type: Grid

Question Q13

Variable Name: Q13

Variable Label: Q13 How often look for information on vaginal inserts

Question Text: How often do you look for information about vaginal inserts or other products from the following sources:

[RANDOM ORDER]

Variable Name	Variable Text	Variable Label
Q13_1	Medical journals	Q13_1 Info: Medical journals
Q13_2	Medical websites or software (e.g. UpToDate, Epocrates, Medscape)	Q13_2 Info: Medical websites or software
Q13_3	Drug company/pharmaceutical representatives or their website	Q13_3 Info: Drug company rep or website
Q13_4	Go online/use a search engine (e.g., Google)	Q13_4 Info: Online search
Q13_5	Professional medical societies (e.g.,	Q13_5 Info: Professional

	publications, guidelines)	medical societies
Q13_6	Conferences	Q13_6 Info: Conferences
Q13_7	Discussion with colleagues (e.g., in person, email)	Q13_7 Info: Discussion w/ colleagues
Q13_8	FDA website or other FDA sources of information (e.g., email, alerts)	Q13_8 Info: FDA
Q13_9	Other government agencies (e.g., NIH, CDC)	Q13_9 Info: Other government agencies

Value	Value Label
1	Never
2	Rarely
3	Sometimes
4	Often

//[SHOW QUESTION AT THE TOP OF THE SCREEN FOR QUESTION 14]//

The next question refers to boxed warnings, commonly referred to as black box warnings, on the product labeling for Vagifem, a vaginal tablet, and other estrogen products.

Question Type: Multi-Punch

Question Q14

Variable Name: Q14

Variable Label: Q14 Primary role of boxed warning

Question Text: In your opinion, what is the primary role of a boxed warning?
Choose up to three options.

//Random Order, except last three

//PROGRAMMING NOTE: ALLOW PARTICIPANT TO UP TO SELECT THREE ANSWERS//

Variable Name	Variable Text	Variable Label
Q14_1	To highlight if the product has risk of serious or life-threatening adverse effects	Q14_1 BW Primary Role: Highlight most serious risks
Q14_2	To provide information that should be factored into a decision to prescribe the product	Q14_2 BW Primary Role: Provide prescribing information
Q14_3	To provide an overview of the safety profile of the product	Q14_3 BW Primary Role: Provide safety profile overview
Q14_4	To disclose clinical trial and other product safety testing information	Q14_4 BW Primary Role: Clinical trial and safety testing

Q14_5	To provide information that prescribers should be communicating to patients	Q14_5 BW Primary Role: Info to communicate to patients
Q14_6	To provide information on how to safely use the product	Q14_6 BW Primary Role: Info on how to safely use product
Q14_7	I do not see a role for them	Q14_7 BW Primary Role: No role for BW
Q14_8	Other (specify)	Q14_8 BW Primary Role: Other
Q14_9	Unsure/Don't know	Q14_9 BW Primary Role: Unsure/Don't know

Value	Value Label
1	Included
0	Not included

//PROGRAMMING NOTE: SHOW PARAGRAPH ON ITS OWN PAGE//

The next set of questions will ask you more specifically about the boxed warning and prescribing information for Vagifem to treat vulvar and vaginal atrophy. This boxed warning appears on all prescription estrogen products.

//PROGRAMMING NOTE: "NEXT" BUTTON TO PROCEED TO Q15//

Question Type: Single Punch

Question Q15

Variable Name: Q15

Variable Label: Q15 Familiarity with BW for Vagifem and other estrogen products

Question Text: How would you rate your familiarity with the boxed warning information for Vagifem and other estrogen products?

Value	Value Label
1	Not at all familiar
2	Slightly familiar
3	Somewhat familiar
4	Familiar
5	Very familiar
-99	Refused

Question Type: Single Select Grid

Question Q16

Variable Name: *Q16*

Variable Label: Q16 Risks recalled from vaginal insert boxed warning

Question Text: Which of the following risks do you recall being included in the boxed warning for vaginal inserts? Please indicate a response for each risk.

[RANDOM ORDER EXCEPT FOR LAST OPTION]

Variable Name	Variable Text	Variable Label
Q16_1	Endometrial cancer	Q16_1 Risks: Endometrial cancer
Q16_2	Endometrial hyperplasia	Q16_2 Risks: Endometrial hyperplasia
Q16_3	Dementia	Q16_3 Risks: Dementia
Q16_4	Stroke	Q16_4 Risks: Stroke
Q16_5	Deep vein thrombosis (DVT)	Q16_5 Risks: Deep vein thrombosis
Q16_6	Breast cancer	Q16_6 Risks: Breast cancer
Q16_7	Gallbladder disease	Q16_7 Risks: Gallbladder disease
Q16_8	Hypercalcemia	Q16_8 Risks: Hypercalcemia
Q16_9	Visual abnormalities	Q16_9 Risks: Visual abnormalities
Q16_10	Elevated blood pressure	Q16_10 Risks: Elevated blood pressure
Q16_11	Other (specify)	Q16_12 Risks: Other

Value	Value Label
1	Included
2	Not included
98	Don't know

//PROGRAMMING NOTE: SHOW PARAGRAPH ON ITS OWN PAGE, THEN CLICK NEXT TO VIEW BOXED WARNING//

We would like to show you some of the boxed warning information for Vagifem, which is available in the FDA-approved prescribing information. This boxed warning information appears on the labeling for all estrogen products. Please take a few moments to review this information.

//PROGRAMMING NOTE: SHOW THE BOXED WARNING ON ITS OWN PAGE, CAPTURE TIME SPENT ON BOXED WARNING//

[View boxed warning information]¹

¹ NIH NLM (2019). LABEL: VAGIFEM- estradiol insert.
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e5ad3cf6-dd96-4e64-af21-c1eee38d0b88>

NDC Code(s): 0169-5176-03, 0169-5176-04, 0169-5176-99

Packager: Novo Nordisk

Category: HUMAN PRESCRIPTION DRUG LABEL

DEA Schedule: None

Marketing Status: New Drug Application

DRUG LABEL INFORMATION

Updated April 9, 2019

If you are a consumer or patient please visit [this version](#).

DOWNLOAD DRUG LABEL INFO: [PDF](#) | [XML](#) 

OFFICIAL LABEL (PRINTER FRIENDLY) 

[VIEW ALL SECTIONS](#)

+ HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VAGIFEM safely and effectively. See full prescribing information for VAGIFEM. Vagifem® (estradiol vaginal inserts) Initial U.S. ...

+ TABLE OF CONTENTS

Table of Contents

- BOXED WARNING [\(WHAT IS THIS?\)](#)

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER AND PROBABLE DEMENTIA

Estrogen-Alone Therapy

Endometrial Cancer

There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding [[SEE WARNINGS AND PRECAUTIONS \(5.3\)](#)].

Cardiovascular Disorders and Probable Dementia

Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia [[SEE WARNINGS AND PRECAUTIONS \(5.2, 5.4\)](#), and [CLINICAL STUDIES \(14.2, 14.3\)](#)].

The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg]-alone, relative to placebo [[SEE WARNINGS AND PRECAUTIONS \(5.2\)](#), and [CLINICAL STUDIES \(14.2\)](#)].

The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg]-alone, relative to placebo [[SEE WARNINGS AND PRECAUTIONS \(5.2\)](#), and [CLINICAL STUDIES \(14.2\)](#)].

The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with daily CE (0.625 mg)-alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women [[SEE WARNINGS AND PRECAUTIONS \(5.4\)](#), [USE IN SPECIFIC POPULATIONS \(8.5\)](#), and [CLINICAL STUDIES \(14.3\)](#)].

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

Estrogen Plus Progestin Therapy

Cardiovascular Disorders and Probable Dementia

Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia [[SEE WARNINGS AND PRECAUTIONS \(5.2, 5.4\)](#), and [CLINICAL STUDIES \(14.2, 14.3\)](#)].

The WHI estrogen plus progestin substudy reported increased risks of DVT, pulmonary embolism (PE), stroke and myocardial infarction (MI) in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral CE (0.625 mg) combined with medroxyprogesterone acetate (MPA) [2.5 mg], relative to placebo [[SEE WARNINGS AND PRECAUTIONS \(5.2\)](#), and [CLINICAL STUDIES \(14.2\)](#)].

The WHIMS estrogen plus progestin ancillary study of the WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with daily CE (0.625 mg) combined with MPA (2.5 mg), relative to placebo. It is unknown whether this finding applies to younger postmenopausal women [[SEE WARNINGS AND PRECAUTIONS \(5.4\)](#), [USE IN SPECIFIC POPULATIONS \(8.5\)](#), and [CLINICAL STUDIES \(14.3\)](#)].

Breast Cancer

The WHI estrogen plus progestin substudy also demonstrated an increased risk of invasive breast cancer [[SEE WARNINGS AND PRECAUTIONS \(5.3\)](#), and [CLINICAL STUDIES \(14.2\)](#)].

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and MPA, and other combinations and dosage forms of estrogens and progestins.

Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

[CLOSE](#)

//PROGRAMMING NOTE: HAVE A “NEXT” BUTTON AT THE BOTTOM OF THE BOXED WARNING PAGE TO PROCEED TO QUESTION 17//

Question Type: Single Punch

Question Q17

Variable Name: Q17

Variable Label: Q17 Usefulness of BW for Vagifem

Question Text: How useful is the information in the boxed warning for Vagifem?

Value	Value Label
1	Not at all useful
2	Slightly useful
3	Somewhat useful
4	Useful
5	Very useful
-99	Refused

Question Type: Single Punch

Question Q18

Variable Name: Q18

Variable Label: Q18 Assessment of risk framing in Vagifem BW

Question Text: What is your assessment of the way the risks of Vagifem are framed in the boxed warning?

Value	Value Label
1	Strongly understates risk
2	Somewhat understates risk
3	Provides appropriate assessment of risk
4	Somewhat overstates risk
5	Strongly overstates risk
6	Other (specify)
-99	Refused

Question Type: Single Punch

Question Q19

Variable Name: Q19

Variable Label: Q19 Assessment of benefits versus risks Post-BW

Question Text: Which statement best reflects your opinion on the relative benefits versus risks of vaginal inserts for patients with vulvar and vaginal atrophy.

Value	Value Label
1	The benefits of vaginal inserts outweigh the risks for most patients
2	The benefits of vaginal inserts outweigh the risks for some, but not most, patients
3	The benefits of vaginal inserts outweigh the risks for very few patients
4	I am not familiar enough with vaginal inserts to make an assessment
-99	Refused

Question Type: Multi-Punch

Question Q20

Variable Name: Q20

Variable Label: Q20 How improve Vagifem boxed warning

Question Text: What would improve the boxed warning for Vagifem, in your opinion? (Select all that apply.)

Variable Name	Variable Text	Variable Label
Q20_1	Nothing, the warning is fine the way it is	Q20_1 Improve BW: Nothing
Q20_2	Better evidence to support risk information	Q20_2 Improve BW: Better risk info evidence
Q20_3	Decrease the amount of information given/fewer words	Q20_3 Improve BW: Decrease amount of info/shorten
Q20_4	Simpler language	Q20_4 Improve BW: Simpler language
Q20_5	Formatting improvements (e.g., use of boldface)	Q20_5 Improve BW: Formatting
Q20_6	Increase the amount of information (e.g., statistics, more details)	Q20_6 Improve BW: Increase amount of info
Q20_7	Other (Specify)	Q20_7 Improve BW: Other (specify)
Q20_8	Make exclusive	Q20_8 Improve BW: Unsure/Don't know

//Q20_8: Make exclusive//

Value	Value Label
1	Included

0	Not included
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Question Type: Open-End Essay

Question Q21

Variable Name: Q21

Variable Label: Q21 Specific feedback on Vagifem BW information

Question Text: Please provide any specific feedback on the boxed warning information for Vagifem.

//PROGRAMMING NOTE: SHOW SENTENCE ON ITS OWN PAGE, THEN CLICK NEXT TO VIEW Q22//

Please now consider boxed warnings in general, not only the one you saw for Vagifem.

Question Type: Grid

Question Q22

Variable Name: Q22

Variable Label: Q22 Degree agree or disagree with BW statements

Question Text: To what degree do you agree or disagree with the following statements about boxed warnings in general (in other words, across all classes of prescription drugs)?

[RANDOM ORDER for 1-6]

Variable Name	Variable Text	Variable Label
Q22_1	Boxed warnings are very common on the products that I prescribe	Q22_1 Agree/Disagree: BW are very common on products I prescribe
Q22_2	Boxed warnings do not generally factor heavily into my decisions on whether to prescribe a product	Q22_2 Agree/Disagree: BW do not generally factor heavily
Q22_3	I think carefully before prescribing a product with a boxed warning if other treatments are available	Q22_3 Agree/Disagree: I think carefully before prescribing BW product if others available
Q22_4	I counsel my patients differently when prescribing a product with a boxed warning	Q22_4 Agree/Disagree: Counsel patients differently with BW
Q22_5	My patients rarely know whether a product would have a boxed warning or not	Q22_5 Agree/Disagree: Patients rarely know if product has BW
Q22_6	My patients are worried or scared when they see boxed warnings	Q22_6 Agree/Disagree: Patients worried/scared when they see BW

Value	Value Label
1	Strongly disagree
2	Disagree
3	Neither agree nor disagree
4	Agree
5	Strongly agree
98	Unsure/Don't know

Question Type: Single Punch

Question Q23

Variable Name: Q23

Variable Label: Q23 General favorability of BW

Question Text: How favorable is your opinion of boxed warnings *in general* (across all classes of prescription drugs)?

Value	Value Label
1	Very unfavorable
2	Somewhat unfavorable
3	Neither unfavorable nor favorable
4	Somewhat favorable
5	Very favorable
98	Unsure/Don't know
-99	Refused

Question Type: Open End Essay

Question Q24

Variable Name: Q24

Variable Label: Q24 Suggestions for better using BW to highlight safety info

Question Text: In general, what suggestions do you have on how to better use boxed warnings as a tool to highlight important safety information?

//PRETEST ONLY//**//DISPLAY TEXT//**

We would like your feedback on the survey that you completed. This will help FDA improve the survey for future use with healthcare providers.

Question Type: Single Punch

Question P1

Variable Name: *P1*

Variable Label: P1 One session completion

Question Text: Were you able to complete the survey in one session?

Value	Value Label
1	Yes
0	No

Question Type: Single Punch

Question P2

Variable Name: *P2*

Variable Label: P2 Participant Experience with Survey

Question Text: How would you rate your experience taking the survey?

Value	Value Label
1	Poor
2	Fair
3	Good
4	Very good
5	Excellent
-99	Refused

Question Type: Open End Essay

Question P3

Variable Name: *P3*

Variable Label: P3 Difficulty answering question

Question Text: Were there any questions you had difficulty answering? If yes, please explain.

Question Type: Open End Essay

Question P4

Variable Name: *P4*

Variable Label: P4 Other feedback

Question Text: What other suggestions of feedback about this survey would you like to share?

//DISPLAY FOR BOTH PRETEST AND MAIN STUDY//

Thank you for taking this survey. Your time is greatly appreciated.