## Perceptions of Prescription Drug Products with Medication Tracking Capabilities

# Questionnaire

OMB Control No. 0910-xxxx Expiration date: xx/xx/xxxx

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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.

#### INTRODUCTION

Thank you for participating in this survey. The survey questions will ask about your opinions and experiences with pharmaceutical marketing materials about prescription drugs. Please answer honestly and give us your best guess on answers you do not know.
[NEXT SCREEN
On the next screen, you will be shown a webpage for a new prescription drug. The researchers are looking at how [people / providers] think about drug information. Take your time looking at the webpage. Carefully read the information presented to see what you think and feel about it. After you finish viewing the webpage, we will ask you some questions about what you saw.
[Utilize randomization procedures provided by Westat]
[]
[VIEWWEBPAGE] Were you able to view the webpage for the prescription drug?
<ol> <li>Yes</li> <li>No [TERMINATE]</li> </ol>
[NEXT SCREEN]
Please answer the following questions based on the information you have just seen.

[Programmer Notes:

1. DO NOT DISPLAY QUESTION HEADINGS,

2. IF A RESPONDENT SKIPS A QUESTION, PROGRAM A REMINDER IMMEDIATELY FOLLOWING THE QUESTION SKIPPED, SUCH AS "You did not answer this question. Your answers are important. If you meant to skip this question, you can click "next" to go to the next question."]

#### **Adherence**

1. [Q1\_HELPPATIENTS] Based on the webpage information that you saw, how likely is it that Sustadia would help patients take their medication as directed?

0	Very unlikely
0	Unlikely
0	Neither likely nor unlikely
0	Likely
0	Very likely

2. [PCPs only] [Q2\_DOCTORSTRACK\_PCP] Based on the webpage information you saw, how effective is Sustadia at helping doctors keep track of when patients take their medication?

0	Extremely effective
0	Very effective
0	Somewhat effective
0	Slightly effective
0	Not at all effective

3. [Consumers only] [Q3\_YOUTRACK\_CON] Based on the webpage information you saw, how effective would Sustadia be at helping you keep track of when to take your medication?

0	Extremely effective
0	Very effective
0	Somewhat effective
0	Slightly effective
0	Not at all effective

4. To what extent do you agree or disagree with the following statements about Sustadia, the medicine that tracks medication use:

	Completely	Agree	Neither	Disagree	Completely
	agree		agree nor		Disagree
			disagree		
[Q4A_EVIDENCE_EFFECTIVE] There is	0	0	О	0	0
evidence that Sustadia, the medicine that					
tracks medication use, is effective in					
helping people manage their diabetes.					
[Q4B_EVIDENCE_HELPS] There is evidence	0	0	0	0	0
that Sustadia, the medicine that tracks					

medication use, helps people take their					
medication as directed.					
[Q4C_BENEFITS_WORTH] The benefits of	0	0	0	0	0
Sustadia, the medicine that tracks					
medication use, are worth the possible					
side effects.					

# **Efficacy - Managing Diabetes**

5. [Consumers only] [Q5\_HOWEFFECTIVE\_CON] Based on the webpage information you saw, how effective would Sustadia be at managing your diabetes?

0	Extremely effective
0	Very effective
0	Somewhat effective
0	Slightly effective
0	Not at all effective

6. [PCPs only] [Q6\_HOWEFFECTIVE\_PCP] Based on the webpage information you saw, how effective would Sustadia be at managing diabetes?

0	Extremely effective
0	Very effective
0	Somewhat effective
0	Slightly effective
0	Not at all effective

# **Manipulation Check**

- 7. [Q7\_EVIDENCE\_MORELIKELY] Based on the information that you saw, is there evidence that people who use Sustadia are more likely to take their medicine as directed?
  - o Yes
  - o No
  - 0 Do not know

## **Risks - Side Effects**

8. Based on the webpage information you saw, what are the **most serious** side effects of Sustadia? Check all that apply.

[RANDOMIZE ORDER]

- o [Q8\_SIDEEF\_NAUSEA] Nausea
- o [Q8\_SIDEEF\_VOMIT] Vomiting
- o [Q8\_SIDEEf\_HEADACHE] Headache
- 0 [Q8\_SIDEEF\_ITCH] Itching or pain where you injected the medicine
- 0 [Q8\_SIDEEF\_WEIGHT] Weight gain
- 0 [Q8\_SIDEEF\_BLOODSUGAR] Low blood sugar
- 0 [Q8\_SIDEEF\_POTASS] Low blood potassium levels
- o [Q8\_SIDEEF\_HEART] Heart failure
- 0 [Q8\_SIDEEF\_ALLERGIC] Serious allergic reactions.
- 9. [Q9\_HOWSERIOUS] In your opinion, how serious are the Sustadia side effects that you selected in the question above?

0	Extremely serious
0	Very serious
0	Somewhat serious
0	Slightly serious
0	Not at all serious

#### **Perceived Risk - Data Privacy**

10. [Q10\_PRIVACYRISK] Based on the webpage information that you saw, how likely is it that the privacy of a person's information would be at risk if they use Sustadia? (ASK to Conditions 1-4 only)

0	Very unlikely
0	Unlikely
0	Neither likely nor unlikely
0	Likely
0	Very likely

## Intention - [PCPs Only]

11. Based on the webpage information that you saw, how likely would you be to:

	Very	Unlikely	Neither likely	Likely	Very likely
	unlikely		nor unlikely		
[Q11A_TALKTOPATIENTS_PCP] Talk to	0	0	0	0	0
your patients about Sustadia?					
[Q11B_PRESCRIBE_PCP] Prescribe	0	0	0	0	0
Sutadia to a patient with diabetes?					
[Q11C_LOOKINFO_PCP] Look for more	0	0	0	0	0
information about Sustadia?					

12. [Q12\_COMFORTPRESCRIBING\_PCP] How comfortable would you be prescribing Sustadia to your patients?

0	Very comfortable
0	Comfortable
0	Neither comfortable nor uncomfortable
0	Uncomfortable
0	Very uncomfortable

# **Intention - [Consumers Only]**

13. Based on the webpage information that you saw, how likely would you be to:

	Very	Unlikel	Neither likely	Likel	Very likely
	unlikely	у	nor unlikely	у	
[Q13A_TALKTODOCTOR_CON] Talk to	0	0	0	0	0
your doctor about Sustadia?					
[Q13B_ASKPRESCRIBE_CON]Ask your	0	0	0	0	0
doctor to prescribe Sustadia for you?					
[Q13C_LOOKINFO_CON] Look for more	0	0	0	0	0
information about Sustadia?					

14. [Q14\_SWITCH\_CON] I would consider switching from my current prescription to Sustadia.

0	Completely agree
0	Agree
0	Neither agree nor disagree
0	Disagree
0	Completely disagree

#### **Disclosure Recall**

15. The following statements **may** or **may not** have been in the webpage you viewed. Please indicate whether you recall seeing the following statements.

## [RANDOMIZE ORDER]

	Yes -	No- Do not	Don't
	Recall	recall	know
	seeing	seeing	
[Q15A_DISCLOSURE_MORELIKELY] In studies, people who used			
Sustadia SmartPen were more likely to take their medication as			

directed than people who used similar medicines without this		
technology. (Show Conditions 1-4)		
[Q15B_DISCLOSURE_NOMORELIKELY] In studies, people who used		
Sustadia SmartPen were no more likely to take their medication as		
directed than people who used similar medicines without this		
technology. (Show Conditions 1-4)		
[Q15C_DISCLOSURE_NOTKNOWN] It is not known whether people		
who use Sustadia SmartPen are more likely to take their medicine as		
directed. (Show Conditions 1-4)		

16. The following statements **may** or **may not** have been in the webpage you viewed. Please indicate whether you recall seeing the following statements.

	Yes -	No- Do not	Don't
	Recall	recall	know
	seeing	seeing	
[Q16A_DISCLOSURE_BUILTIN] The Sustadia SmartPen has built-in			
digital technology that helps you and your doctor keep track of when			
you take your medicine and how much you take. (Show Conditions			
1-4)			
[Q16B_DISCLOSURE_APPVIEW] The information goes to an app that			
you and your doctor can view on a smartphone or tablet. (Show			
Conditions 1-4)			
[Q16C_DISCLOSURE_REMINDERS] The Sustadia SmartPen provides			
helpful reminders and alerts (Show Conditions 1-4)			
[Q16D_DISCLOSURE_DATETIME] Sustadia captures the date and			
time the medication was taken. (Show Conditions 1-5)			
[Q16E_DISCLOSURE_FINDBALANCE] Get closer to finding your			
balance with Sustadia. (Show Conditions 1-5)			
[Q16F_DISCLOSURE_BLOODSUGARCONTROL] When you have type 2			
diabetes, you know that keeping your blood sugar under control is a			
balancing act. (Show Conditions 1-5)			

# Credibility

17. [Q17\_CONFIDENTACCURACY] How confident are you in the accuracy of the information presented on the website?

0	Very confident
0	Confident
0	Neither confident nor unconfident
0	Unconfident
0	Very unconfident

18.	018	TRUEFALSE	To what extent do	vou believe	this statement is true?
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The Sustadia SmartPen built-in digital technology can help people, and their doctors, keep track of when they take their medicine. (Conditions 1-4)

0	Definitely false
0	Probably false
0	Neither true nor false
0	Probably true
0	Definitely true

19. [Q19\_MISLEADEFFECTIVENESS] Would this webpage mislead people about the **effectiveness** of Sustadia?

0	Definitely not
0	Probably not
0	Neither yes nor no
0	Probably yes
0	Definitely yes

20. [Q20\_MISLEADRISKS] Would this webpage mislead people about the risks of Sustadia?

0	Definitely not
0	Probably not
0	Neither yes nor no
0	Probably yes
0	Definitely yes

## **Other: Open-ended**

- 21. [Q21\_OPENEND\_WHATBENEFITS] Based on the webpage information that you saw, what are the benefits of Sustadia?
- 22. [Q22\_OPENEND\_ADHERENCE] When thinking about prescription drugs, what does "adherence" mean to you?

23. [Q23\_OPENEND\_OTHERINFO] What other information would you like to know about Sustadia?

#### **Attitudes and Beliefs**

We are now done asking you about the webpage that you looked at today. We would like to ask you about your personal experience and views on technology and prescription drugs.

24. <u>TO24\_FAMILIARITY</u> How familiar are you with medications with built-in technology that help patients and their doctors keep track of when they take their medication and how much they take?

0	Extremely familiar
0	Very familiar
0	Somewhat familiar
0	Slightly familiar
0	Not at all familiar

- 25. [Consumers Only] [025\_EVERUSED] Have you ever used a medication with built-in technology that helps you and your doctor keep track of when you take your medication and how much you take?
  - o Yes
  - o No
- 26. [PCPs Only] [Q26\_EVERPRESCRIBED] Have you ever prescribed a medication with built-in technology that helps you keep track of when patients take their medication and how much they take?
  - o Yes
  - o No

27. To what extent do you agree or disagree with each of the following statements?

	Completely agree	Agree	Neither agree nor disagree	Disagree	Completely Disagree
[Q27A_EASYTOUSE] Technology that helps people take their medication as prescribed would be easy to use.	0	0	0	0	0
[Q27B_APPREHENSIVE] (I/Most of my patients) would be apprehensive about	0	0	0	0	0

using technology to track (my/their) medication use.					
[Q27C_IMPROVECOMMUNICATIONS] Technology that helps (me/patients) take medication as directed would improve communication with my [healthcare provider/patients]	0	0	0	0	0
[Q27D_INFOSECURE_CON] Information collected with technology, about my medication use, would be kept secure and private. (Consumers only)	0	0	0	0	0
[Q27E_TIMECONSMING_PCP] Using technology to monitor my patients' medication use would be too time consuming. (PCPs only)	0	0	0	0	0
[Q27F_NEEDHELP] (I/My patients) need help taking medication as directed.	0	0	0	0	0

# **Consumer Demographics**

Finally, we would like to ask you a few questions about yourself. This section will help us determine how representative the participants are who complete this questionnaire.

- 28. [Q28\_HEALTH\_CON] In general, would you say your health these days is:
- o Excellent
- 0 Very good
- o Good
- o Fair
- 0 Poor
- 29. [Q29\_YEARSPRESCRIPTION\_CON] For how many years have you taken prescription drug(s) for diabetes?

Choose an item [DROP DOWN MENU WITH YEARS, STARTING WITH 'Less than 1 year.']
-Less than 1 year

- 1
- 2

- 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10

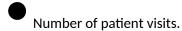
- 11 to 19

- 20 or more
  - 30. [Q30\_EDUCATION\_CON] What is the highest level of education that you have completed? Please select one.
    - O Less than high school
    - **o** High school graduate or equivalent (for example: GED)
    - **o** Some college, but no degree
    - **o** Associate or two-year college degree
    - **o** Bachelor's degree (for example: BA, AB, BS)
    - Advanced or post-graduate degree (for example: Master's degree, MD, DDS, JD, PhD, EdD)
- 31. [Q31\_STATE\_CON] In which state do you currently live? [DROP DOWN MENU OF STATES BELOW ]

#### **Provider Demographics**

Finally, we would like to ask you a few questions about yourself. This section will help us determine how representative the participants are who complete this questionnaire.

32. [Q32\_NUMBERPATIENTS\_PCP] During your last normal week of practice, how many patient visits did you have at all office locations?



33. [Q33\_NUMBERPRESCRIPTIONS\_PCP] Approximately, how many prescriptions do you write in a typical week?



Number of prescriptions per week.

34. [Q34\_STATEPRACTICE\_PCP] In which state is your practice based? [SEE DROP DOWN MENU OF STATES BELOW]

35. [Q35\_URBANRURAL\_PCP] Is your practice located in an urban, suburban, or rural area?

- o Urban
- o Suburban
- o Rural



36. [Q36\_TYPEOFPRACTICE\_PCP] Which of the following best describes the practice location you work in most often (i.e., where you spend the most hours per week)? Please select one.

- O Private solo or group practice
- O Freestanding clinic/urgent care (not part of a hospital outpatient department)
- o Non-Federal Government clinic (e.g., state, county, city, maternal and child health, etc.)
- o Federal Government operated clinic (e.g., Veterans Affairs, military, etc.)
- O Health maintenance organization or other prepaid practice (e.g., Kaiser Permanente)
- O Community Health Center (e.g., Federally Qualified Health Center (FQHC), federally funded clinics or "look alike" clinics)
- O Other, please specify \_\_\_\_\_

## **Consumer Debriefing**

Thank you for completing the questionnaire. Sustadia is not a real product and it is not available for sale. The purpose of this research is to understand how people think about information in prescription drug advertisements. In order to get an unbiased reaction to this information, we created a brand for this study. Please see your healthcare professional for questions about diabetes. This study was sponsored by the U.S. Food & Drug Administration (FDA).

Please click the submit button to complete the survey.

**PCP Debriefing** 

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