OMB Control No: 0910-0497 Expiration Date: 10/31/2020

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 valid OMB control number. The valid OMB control number for this information collection is 0910-0497. The time required to complete this portion of the information collection is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, 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.

Consumer Focus Group Screening Questionnaire Prescription Drug Promotion Perspectives

	Segment	Washington, DC	Atlanta, GA	Total
Consumers	Those with a high school education/GED or less	12 (1 group)	12 (1 group)	24
	Those with above a high school education	12 (1 group)	24 (2 groups)	36
Total		24	36	60

groups, one in Washir education/GED	gton DC and one in Atlanta, will be conducted with those with no more than a high school
Hello, this is speak to	from [RECRUITMENT FIRM NAME], a market research firm. May I please?
sponsored by the	king with RTI International, a nonprofit research organization on a research study Food and Drug Administration, or FDA, and would like to get your opinions about and prescription drug promotions. We are not selling any products.

Note. We will recruit 12 individuals per focus group with the expectation that 9 participants are present for each session. Two

We are holding a focus group on [DATE]. The focus group starts at [TIME] and will last about 90 minutes. The discussion will be audio recorded, and project team members may observe the discussion in person or remotely (via live-streaming). You will receive a token of appreciation of \$100 for participating in the focus group.

Can I as	sk you a few questions now to see if you qualify?
	Yes - Continue

No – Thank the adult and end call.

Market Research Exclusion

1.	Have you ever worked for? [READ LIST]
	Any office, division, or agency within the Department of Health and Human Services (HHS) > TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
	A healthcare company or in the healthcare field → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
	A pharmaceutical company → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
	A marketing or market research company → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
2.	Have you participated in an interview or focus group in the past 3 months? [READ LIST]
	Yes → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
	No → Continue
<u>De</u>	mographics
3.	What is your gender? [RECRUIT A MIX]
	Male
	Female
4.	What is your age? [RECRUIT A MIX]
	18 - 20 years of age
	21 – 30 years of age
	31 - 40 years of age
	41 - 50 years of age
	51 – 60 years of age > 60 years of age
	> 60 years or age
5.	Are you of Hispanic or Latino origin?
	Yes
	No
,	
6.	What is your race? [SELECT ALL THAT APPLY] [READ LIST IF NECESSARY AND RECRUIT A MIX]
	White
	Black or African American
	Asian
	Native Hawaiian or Other Pacific Islander
	American Indian or Alaskan Native

/.	What is the highest level of education that you have completed? [RECRUIT HIGH SCHOOL OR LESS FOR ONE SEGMENT and ABOVE HIGHSCHOOL FOR OTHER SEGMENT]
	Less than high school diploma High school graduate or GED Some college or 2-year degree College degree Postgraduate degree
8.	During the focus group discussion, you will be asked to review written materials and offer your opinions, so I need to ask whether you have a medical or nonmedical condition that affects your ability to read and/or understand written materials in English.
	Yes → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT] No → Continue
	For study purposes, if you participate, the focus group will be audio recorded and the video will be live streamed to study team members. Are you okay with us audio recording and live streaming the focus group?
	Yes → Continue No → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
Clo	sing Scripts
<u>Inel</u>	igible - Closing Script
elig	sorry, but you are not eligible for this study. There are many possible reasons why people are not ible. These reasons were decided earlier by the researchers. However, thank you for your interest in study and for answering our questions today.
Elig	ible – Closing Script
abo	at! You qualify for our study. The discussion group will be held on [DATE] at [TIME] and will last ut 90 minutes. You will receive a token of appreciation of \$100 at the end of the focus group for your cicipation. If you use reading glasses or hearing aids, please be sure to bring them with you.
Wo	uld you like to participate in the group discussion at [TIME] on [DATE]?
	Yes → Continue to scheduling script. No → Thank the adult and end call.
Elig	ible - Scheduling script

May I please have your mailing and/or e-mail address and telephone number to send you a confirmation letter with directions for attending the focus group on [DATE/TIME]? We will use this information to send you a reminder letter and to call and remind you of the focus group. We will destroy all contact information at the conclusion of the focus groups. [VERIFY CONTACT INFORMATION]

Follow-up

NOTE THIS PAGE MUST BE STORED SEPARATELY FROM THE SCREENER AND DATA. PLEASE DESTROY UPON COMPLETION OF FOCUS GROUPS.

NAME:	
ADDRESS:	
CITY:	
ZIP CODE:	
E-MAIL	
What is the best time to reach you? What is the best telephone number to reach you at that tim	ie?
BEST TIME TO BE REACHED:	
BEST PHONE NUMBER:	
Is there another time and number we can try if we miss you?	
ALTERNATE TIME:	
ALTERNATE PHONE NUMBER:	

Thank you. That's all the questions I have today. If you have any questions or find that you are unable to attend, please call [recruiter's phone number] as soon as possible. Thank you again for your participation. We look forward to seeing you at [TIME] on [DATE].

Healthcare Provider Focus Group Screening Questionnaire Prescription Drug Promotion Perspectives

	Segment	Washington, DC	Atlanta, GA	Total
Healthcare Providers	Primary Care Providers (general medicine & internal medicine practitioners)	12 (1 Group)	12 (1 group)	24
	Advanced Practitioners (NPs & PAs with prescribing authority	12 (1 group)	12 (1 group)	24
Total		24	24	48

Note. We will recruit 12 individuals per focus group with the expectation that 9 participants are present for each session.

Hello, this is from [RECRUITMENT FIRM NAME], a market research firm. May I please speak to?
Hello. We are working with RTI International, a nonprofit research organization on a research study sponsored by the Food and Drug Administration, or FDA, and would like to get your opinions about prescription drugs and prescription drug promotions. We are not selling any products.
We are holding a focus group on [DATE]. The focus group starts at [TIME] and will last about 90 minutes. The discussion will be audio recorded, and project team members may observe the discussion in person or remotely (via live-streaming). You will receive a token of appreciation of \$300 for participating in the focus group.
Can I ask you a few questions now to see if you qualify?
Yes – Continue No – Thank the adult and end call.
Healthcare Provider Background Information
Do you currently work as a healthcare provider? Yes
No → TERMINATE [GO TO INFLIGIBLE CLOSING SCRIPT]

2.	What type of healthcare provider are you?
	Doctor of Medicine (MD) → Continue to Q4 [Consider for Primary Care Provider Group] Doctor of Osteopathic Medicine (DO) → Continue to Q4 [Consider for Primary Care Provider Group] Nurse Practitioner (NP) → Continue to Q3 [Consider for Advanced Practitioner Group] Physician's Assistant (PA) → Continue to Q3 [Consider for Advanced Practitioner Group] Other (specify) [Free Text Entry] → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
3.	Do you have prescribing authority?
	Yes → CONTINUE TO Q5 No → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
4.	Do you currently work in general practice, family medicine, or internal medicine?
	Yes → CONTINUE TO Q5 No → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
5.	Do you currently engage in direct patient care at least 50% of the time?
	Yes No → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
6.	How many years have you been engaged in direct patient care (this is defined as at least 50% of time spent in direct patient care)? → [RECRUIT A MIX]
	1-5 years 6-10 years 10-15 years 15-20 years > 20 years
<u>Ma</u>	arket Research Exclusion
7.	Have you ever worked for? [READ LIST]
	Any office, division, or agency within the Department of Health and Human Services (HHS) > TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
	A pharmaceutical company → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT] A marketing or market research company → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]

ο.	Have	you participated in an interview or focus group in the past 3 months? [READ LIST]
		Yes → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT] No → Continue
		No 3 continue
<u>De</u>	mogra	<u>phics</u>
9.	What	is your gender? [RECRUIT A MIX]
		Male
		Female
10.	What	is your age? [RECRUIT A MIX]
		18 - 20 years of age
		21 – 30 years of age
		31 - 40 years of age 41 - 50 years of age
	Н	51 – 60 years of age
		> 60 years of age
11.	Are y	ou of Hispanic or Latino origin?
		Yes
		No
12.	. What	is your race? [SELECT ALL THAT APPLY] [READ LIST IF NECESSARY AND RECRUIT A MIX]
		White
		Black or African American
		Asian
		Native Hawaiian or Other Pacific Islander
		American Indian or Alaskan Native
13.	For st	cudy purposes, if you participate, the focus group will be audio recorded and the video will be
		treamed to study team members. Are you okay with us audio recording and live streaming the group?
		Yes → Continue
		No → TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]
		-

Closing Scripts

Ineligible - Closing Script

I'm sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for answering our questions today.

Eligible - Closing Script

Great! You qualify for our study. The discussion group will be held on [DATE] at [TIME] and will last about 90 minutes. You will receive a token of appreciation of \$300 at the end of the focus group for your participation. If you use reading glasses or hearing aids, please be sure to bring them with you.

Would you like to participate in the group discussion at [TIME] on [DATE]?			
Yes → Continue to scheduling script. No → Thank the adult and end call.			

Eligible - Scheduling script

May I please have your mailing and/or e-mail address and telephone number to send you a confirmation letter with directions for attending the focus group on [DATE/TIME]? We will use this information to send you a reminder email and to call and remind you of the focus group. We will destroy all contact information at the conclusion of the focus groups. [VERIFY CONTACT INFORMATION]

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ADDRESS:
CITY:
ZIP CODE:
E-MAIL
What is the best time to reach you? What is the best telephone number to reach you at that time?
BEST TIME TO BE REACHED:
BEST PHONE NUMBER:
Is there another time and number we can try if we miss you?
ALTERNATE TIME:
ALTERNATE PHONE NUMBER:

Thank you. That's all the questions I have today. If you have any questions or find that you are unable to attend, please call [recruiter's phone number] as soon as possible. Thank you again for your participation. We look forward to seeing you at [TIME] on [DATE].