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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 <u>PRAStaff@fda.hhs.gov</u>.

This study is being conducted on behalf of the U.S. Food and Drug Administration by UserWise, Inc. and San Jose State University.

End of Session Questionnaire

Next, I would like to have you look at some health information and then answer a few questions about that information. It is expected that this should take approximately 4-10 minutes.

Please note that these questions have no impact on your eligibility or compensation and are for informational purposes, only.

* Required

1. Participant ID (the Moderator will enter this) *

Nutritional Facts Survey

Please note that these questions have no impact on your eligibility for compensation and are for informational purposes, only.

The image below shows information on the back of a container of a pint of ice cream. Using this image provided, please answer the following questions. You may use the calculator made available <u>to</u> you if needed for any of the questions.

Ice Cream Nutritional Facts:

Nutrition Facts	
Serving Size	1/2 cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	
Sat Fat 9g	
Cholesterol 28mg	
Sodium 55mg	2%
Total Carbohydrate 30g	
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%
Percentage Daily Values (DV) are based on a
2,000 calorie diet. Your daily	이 같은 것 같은
be higher or lower depending calorie needs.	on your
Ingredients: Cream, Skim	Milk Liquid
Sugar, Water, Egg Yolks, Brow	이 이 것 같은 것 같은 것이 있다. 이 것 같은 것
Milkfat, Peanut Oil, Sugar, But	
Ailkfat, Peanut Oil, Sugar, But Carrageenan, Vanilla Extract.	ter, Salt,

2. The image above shows information on the back of a container of a pint of ice cream. If you eat the entire container, how many calories will you eat? * Please enter a numerical value (no commas or decimals)

3. If you are allowed to eat 60 grams of carbohydrates as a snack, how many cups of ice cream could you have? *

Please select the value in cups from the dropdown list *Mark only one oval*.

\bigcirc	None
\bigcirc	1/4 cup
\bigcirc	1/2 cup
\bigcirc	3/4 cup
\bigcirc	1 cup
\bigcirc	1 and $1/4$ cups
\bigcirc	1 and $1/2$ cups
\bigcirc	1 and $3/4$ cups
\bigcirc	2 cups
\bigcirc	2 and $1/4$ cups
\bigcirc	2 and $1/2$ cups
\bigcirc	2 and $3/4$ cups
\bigcirc	3 cups
\bigcirc	3 and $1/4$ cups
\bigcirc	3 and $1/2$ cups
\bigcirc	3 and $3/4$ cups
	1

- \rightarrow 4 cups
- 4. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day? *

Please enter a numerical value (no commas or decimals)

5. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving? *
Please enter a numerical value (no commas or decimals, no percentage sign)

6. Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings. Is it safe for you to eat this ice cream? *

Mark only one oval.

$ \subseteq $	\supset	Yes
	\geq	No

Not sure

7. (if you answered no to Question 5a) What allergy would make it unsafe to eat this ice cream? *

Mark only one oval.

- O Penicillin allergy
- Peanut allergy
- Latex glove allergy
- Bee sting allergy

Additional Demographics

Please note that these questions have no impact on your eligibility for compensation and are for informational purposes, only.

8. What is your ethnicity? *

Note: this is an excerpt from the 2020 census program. *Mark only one oval.*

- ☐ American Indian or Alaska Native
- 🔵 Asian
- ☐ Black or African American
- Hispanic or Latino
- Native Hawaiian or other Pacific Islander
- ─ White
- \square I prefer not to disclose
- Other: _____

9. Is English your first language?

Mark only one oval.

- Yes
- D No
- Other: _

10. If English is not your first language, what language is?

11. Which is your dominant hand? *

Mark only one oval.

🔵 Right

- C Left
- Ambidextrous

12. Do you normally wear glasses or contact lenses? *

Mark only one oval.

- Yes, and I had them available for the study session(s)
- Yes, and I did NOT have them available for the study session(s)
- 🔵 No

13. Are you color blind? *

Mark only one oval.

- D Yes
- 🗩 No
- Not sure
- 14. How tired are you feeling today? *

Mark only one oval.

- 1 Not at all tired
- \bigcirc 2 Slightly tired
- → 3 Moderately tired
- 4 Very tired
- 15. At the start of the study session today, what level of stress were you feeling? * *Mark only one oval.*
 - 1 Not at all stressed
 - ─ 2 Slightly stressed

 - → 4 Very stressed
 - ⊃ 5 Extremely stressed

Note: These next questions are only applicable if you participated in two study sessions. If you only participated in one session, <u>please proceed to</u> <u>"Next."</u>

- 16. (if you participated in two study sessions) Has your level of stress changed from the start of the first session to the start of the second session? *Mark only one oval.*
 - \square 1 Much worse
 - 2 Somewhat worse
 - \bigcirc 3 Stayed the same
 - ➡ 4 Somewhat better
 - ⊃ 5 Much better

17. (if you participated in two study sessions) How tired were you feeling today, compared to how you felt during your first session?

Mark only one oval.

- 1 Much worse
- 2 Somewhat worse
- □ 3 Stayed the same
- 4 Somewhat better
- \bigcirc 5 Much better

18. (if you participated in two study sessions with a one-hour break) What did you do, during your break?

Check all that apply.

- Checked emails or texts
- Played games on my phone
- Read a book or magazine
- Watched a show/movie
 - Worked on documents on a computer
- Surfed the Web
- Talked on the phone
- Other:

Ease of Use Ratings (as time permits)

Please rate the ease of each task performed from 1 - Very Difficult to 5 - Very Easy. If you did not perform the task described, please choose "I did not perform this task." Please rate these tasks, based on initial intuition, and do not think too hard about any task rating.

If you are out of time for your session, please submit the previous sections and let the Moderator know.

19. Set the pump date/time/year

- 1 Very Difficult
- \bigcirc 2 Difficult
- \supset 3 Neutral
- \rightarrow 4 Easy
- \bigcirc 5 Very Easy
- I did not perform this task

20. Clean the vial septum with an alcohol pad

Mark only one oval.

- 1 Very Difficult
 - 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- 🔘 5 Very Easy
- I did not perform this task

21. **Open the reservoir packaging**

Mark only one oval.

- 1 Very Difficult
- \bigcirc 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- **5** Very Easy
- I did not perform this task

22. Extend reservoir plunger rod

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \supset 3 Neutral
- $2 \quad 4 Easy$
- 🔵 5 Very Easy
- I did not perform this task

23. Attach transfer guard/reservoir to the vial

Mark only one oval.

- 1 Very Difficult
- \bigcirc 2 Difficult
- \supset 3 Neutral
- 2 4 Easy
- **5** Very Easy
- I did not perform this task

24. **Press down on the plunger to pressurize the vial** *Mark only one oval.*

- 1 Very Difficult
- \bigcirc 2 Difficult
- \bigcirc 3 Neutral
- \square 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

- 25. Flip the vial over and pull the plunger to fill the reservoir *Mark only one oval.*
 - 1 Very Difficult
 - \square 2 Difficult
 - \bigcirc 3 Neutral
 - 🔵 4 Easy
 - 5 Very Easy
 - I did not perform this task
- 26. **Tap the reservoir to remove air bubbles and fill the reservoir to the desired volume** *Mark only one oval.*
 - 1 Very Difficult
 - \bigcirc 2 Difficult
 - \bigcirc 3 Neutral
 - D 4 Easy
 - **5** Very Easy
 - I did not perform this task

27. Disconnect the reservoir from the transfer guard

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \bigcirc 3 Neutral
- 2 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

28. Disconnect the transfer guard from the vial and dispose of the transfer guard *Mark only one oval.*

- 1 Very Difficult
- 2 Difficult
- \supset 3 Neutral
- $2 \quad 4 Easy$
- **5** Very Easy
- I did not perform this task

29. Connect the reservoir to the infusion set

- 1 Very Difficult
- \bigcirc 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

30. Remove air bubbles from the reservoir

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

31. Disconnect the plunger from the reservoir

Mark only one oval.

- 1 Very Difficult
- \bigcirc 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- **5** Very Easy
- I did not perform this task

32. Insert the reservoir into the pump

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \supset 3 Neutral
- $2 \quad 4 Easy$
- D 5 Very Easy
- I did not perform this task

33. Fill the infusion set tubing

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \supset 3 Neutral
- \rightarrow 4 Easy
- **5** Very Easy
- I did not perform this task

34. Select the injection site

- 1 Very Difficult
- \bigcirc 2 Difficult
- \bigcirc 3 Neutral
- $2 \quad 4 Easy$
- 🔵 5 Very Easy
- I did not perform this task

35. Wash hands

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- 2 3 Neutral
- 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

36. Clean the injection site with an alcohol pad

Mark only one oval.

- 1 Very Difficult
- \bigcirc 2 Difficult
- D 3 Neutral
- 🔵 4 Easy
- **5** Very Easy
- I did not perform this task

37. Place the infusion set into the insertion device

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

38. Remove the adhesive backing from the infusion set

Mark only one oval.

- 1 Very Difficult
- \bigcirc 2 Difficult
- \supset 3 Neutral
- $2 \quad 4 Easy$
- **5** Very Easy
- I did not perform this task

39. Pull back handle on the insertion device to set the insertion device *Mark only one oval.*

- 1 Very Difficult
- 2 Difficult
- 3 Neutral
- \square 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

40. **Remove the needle guard from the infusion set**

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- 🔵 5 Very Easy
- I did not perform this task

41. Insert infusion set, using the insertion device

Mark only one oval.

- 1 Very Difficult
- \bigcirc 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- **5** Very Easy
- I did not perform this task

42. Secure the adhesive to the skin

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \bigcirc 3 Neutral
- 2 4 Easy
- **5** Very Easy
- I did not perform this task

43. Remove needle from infusion set

Mark only one oval.

- 1 Very Difficult
- 2 Difficult
- \rightarrow 3 Neutral
- \rightarrow 4 Easy
- **5** Very Easy
- I did not perform this task

44. **Place guard on and dispose of needle hub** *Mark only one oval.*

- 1 Very Difficult
- \bigcirc 2 Difficult
- \bigcirc 3 Neutral
- 🔵 4 Easy
- 5 Very Easy
- I did not perform this task

45. Fill the cannula

Mark only one oval.

- 00 1 - Very Difficult
 - 2 Difficult
 - 3 Neutral
 - 4 Easy
- 5 Very Easy
- I did not perform this task

Program basal rates 46.

Mark only one oval.

- 1 Very Difficult \bigcirc
 - 2 Difficult
 - 3 Neutral
 - 4 Easy
- 5 Very Easy
- I did not perform this task

47. Remove and dispose of the infusion set and reservoir

- 1 Very Difficult
- 2 Difficult
- 3 Neutral
- 4 Easy
- 5 Very Easy
- I did not perform this task