OMB Control Number 0910-0891 Dietary Supplement Claims One-on-one In-depth Interview Study Attachment 4 – Consent form

OMB No: 0910-0891 Expiration Date: 8/31/2023

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 0910-0891. The time required to complete this information collection is estimated to average 3 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.

# **Study Participant Consent Form**

# **Purpose:**

- You are being asked to take part in a research study for the U.S. Food and Drug Administration (FDA).
- Westat, an independent social science research firm, is conducting the study on behalf of the FDA.
- The purpose of the study is to help FDA gather consumer inputs to provide accurate and useful product labels for the protection and promotion of public health.

### What is involved:

- You are being asked to be participate in an interview about your attitudes, beliefs, and experiences with certain food products.
- The interview will take approximately 60 minutes.

## **Confidentiality:**

- Your name and information will be kept private to the extent provided by law.
- We will audio record the interview to make sure we hear everything you say correctly.
- Project staff from FDA and Westat may be observing the discussion.
- What you say will not be connected with your name. We will report our results in a summary report. We may use quotes you say in our report, but we won't use your name.
- Study information will be kept in password protected files on secure servers at Westat and FDA locations. No information that can identify you will be given to FDA.
- The data collected in this study will be destroyed no later than three years after the project is completed.

### **Risks:**

- This study is completely voluntary.
- You can stop participating at any time.
- There are no known risks for participation in this research activity.

#### **Benefits:**

- There are no direct benefits to you for participating in this study.
- You will be helping with an important research project.

## **Questions:**

- If you have questions about the project, you may contact the Westat Project Director, Dr. Cynthia Robin at <a href="mailto:cynthiarobins@westat.com">cynthiarobins@westat.com</a>, 610.593.7389, or 240.367.4753.
- If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your first name, the name of the research study (FDA CBD Interviews) that you are calling about, and a phone number beginning with the area code. Someone will return your call as soon as possible.

You will receive \$60 as a token of appreciation for your participation in the study.