

## **Update for Projects using Umbrella Generic Clearance 0910-0847 (Data to Support Social and Behavioral Research as Used by FDA)**

### **Project Title: Consumer Knowledge of Drug Quality**

The FDA Safe Use Initiative awarded a contract via the Broad Agency Announcement to investigate how U.S. Consumers perceived drug quality and whether this perception varies by demographic subgroup and type of product (prescription branded, prescription generic, or over-the-counter (OTC) product).

#### **What was the Problem to be Investigated?**

Patients may contemplate the efficacy and safety of a drug when considering treatment, but they may not think about the quality of a drug. Also, patients may have different concepts of “quality.” To one person, “quality” may refer to the shape and consistency of the pills, while another thinks about “quality” in terms of purity. In addition, patient trust of generic drug quality varies. Several studies have found, for example, that consumers from lower educational and socioeconomic levels trust generics less. Thus, understanding and assessing a drug product’s quality is very challenging for patients.

WebMD conducted an approximately 10-minute survey of its consumer visitors to measure their understanding of and attitudes toward drug product quality for prescription and OTC drugs. The survey addressed what drug quality means to consumers and whether they understand basic drug product manufacturing quality, the FDA’s role in drug quality regulation and drug approval, and how manufacturing quality can affect drug approval. The analysis improved FDA’s understanding of consumer views toward drug quality and how these views differ by demographics, prior knowledge of FDA quality processes, personal use of therapeutic drugs, and other factors.

#### **Method used to Obtain the Sample**

Respondents were randomly selected to take a survey, with no topic identified, on WebMD.com (desktop and mobile). To complete the survey, respondents were required to report that they were a US resident aged  $\geq 18$  years. Standard quality control measures included checking for clear question wording, proper question ordering, and use of appropriate scales and response categories. In addition, during the survey period, the survey was checked to make certain that respondents were answering all questions logically and that skip pattern programming was working properly.

#### **Total Burden**

It is estimated that the survey took 10 minutes to complete. There were 3037 participants. The total burden for this collection was estimated to be 506.2 hours (3037 participants x 10 minutes).