FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

.

TITLE OF INFORMATION COLLECTION: Study on Physician Knowledge of Drug Quality

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The *FDA Strategic Plan for Regulatory Science* identifies nine priority areas for which new or enhanced engagement in regulatory science research is essential to advancing the agency's regulatory mission. One of these priority areas is to *Support New Approaches to Improve Product Manufacturing and Quality*. While an essential regulatory mission of FDA is to ensure that pharmaceutical drug products are safe, effective, and held to Current Good Manufacturing Practices (CGMP), studies suggest that consumers have limited awareness of how FDA ensures these objectives are met. Furthermore, consumers have difficulty assessing the objective quality of drugs, and perceptions of generic drug quality may differ by consumers' demographic attributes.

   In this study, WebMD Health Corp (WebMD) will conduct an approximately 10-minute survey of physicians to measure their understanding of, and attitudes toward, drug product quality. The study will: (1) Analyze physicians' perceptions of prescription drug quality overall and for brand and generic products; (2) Evaluate whether perceptions of drug quality differ by physician specialty; and (3) investigate physician awareness of the FDA's role as the agency that regulates manufacturing quality, and whether this awareness influences perceptions of drug quality and other factors relative to drug safety and efficacy.

2. **Intended use of information:**

   This study will inform FDA – notably, the Office of Pharmaceutical Quality (OPQ) – of physician understanding of and attitudes toward drug product quality, and whether these views differ by physician specialty. This information may be used to guide future public-facing communication strategies from FDA.

3. **Description of respondents:**

   Physicians will be recruited from Medscape physician members. Specifically, the following categories of physicians will be surveyed:

   - 400 primary care physicians
   - 50 cardiologists
   - 50 orthopedics
   - 50 rheumatologists
   - 50 dermatologists
   - 50 endocrinologists

4. **Date(s) to be conducted:**

   October 18, 2018 to December 24, 2018

5. **How the information is being collected:**

   Medscape physician members will be notified of the opportunity to participate in a research survey.

6. **Confidentiality of respondents:**

   The survey will not ask for any personally identifiable information, and responses to the survey will not be disclosed with any information that can be used to personally identify respondents. The information obtained from all the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

   All respondents are subject to WebMD's privacy policy, and will be given a link to the privacy policy before taking the survey. WebMD does not share personally identifiable information ("Personal Information") for government projects. Respondent identity and information will remain private to the extent permitted by law.

   As a nationally known organization, WebMD takes privacy and security extremely seriously. WebMD utilizes a multi-layered approach to security by implementing security controls at the physical, network, system, and application levels.

7. **Amount and justification for any proposed incentive:**

   No honoraria or incentives will be offered for survey participation.

8. **Questions of a Sensitive Nature**

   Survey questions are designed to assess general knowledge and views of drug quality, and are not perceived to be sensitive in nature.

9. **Description of Statistical Methods**

   A total of 650 respondents will be surveyed.

BURDEN HOUR COMPUTATION:

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Survey respondents (physicians)	650	10	108

*Participation time estimated 12 minutes for each survey. Burden hours calculated (No. of respondents * Participation time (minutes) / 60) and then rounded to nearest integer.*

REQUESTED APPROVAL DATE: July, 2018.

NAME OF PRA ANALYST & PROGRAM CONTACT:

PRA Analyst: Ila S. Mizrachi
301-796-7726
Ila.Mizrachi@fda.hhs.gov

Program Contact: Christopher O. St. Clair
301-796-4740
Christopher.StClair@fda.hhs.gov

FDA CENTER: Center for Drug Evaluation and Research (FDA/CDER)