United States Food and Drug Administration

Small Dispensers Assessment under the Drug Supply Chain Security Act

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part B. Statistical Methods

1. Respondent Universe and Sampling Methods

This information collection supports the requirement under section 582(g)(3) of the Food Drug and Cosmetic Act (FD&C Act) for the Food and Drug Administration (FDA, us, or we) to enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees (FTEs) conducting interoperable, electronic tracing of products at the package level.

The DSCSA Small Dispensers Assessment project will recruit individuals representing small dispensers with a total of 25 or fewer FTEs (small dispenser) and individuals representing small dispensers' third-party entities (e.g., solution providers, wholesale distributors, consultants). Within this group, no targeted sampling or respondent selection method will be used as we do not have reason to believe significant differences exist that are dependent upon respondent selection methodology.

Participants will be drawn from our existing industry stakeholder list. We plan to invite respondents to participate in the assessment by sending an email. We estimate that we will send 18,430 emails to companies on our existing list. Participants will be volunteers.

We do not have rationale for a quantitative estimate of response rate. However, we have been working with both the American Pharmacists Association (APhA) and the National Community Pharmacists Association (NCPA) to spread awareness among their membership to promote completion of the assessment questionnaire by qualified pharmacies. These organizations have already offered to assist. NCPA estimates that 95% of their 19,400 independent pharmacy member locations (18,430) have 25 or fewer FTEs. APhA's membership comprises of pharmacists, student pharmacists and pharmacy technicians in all practice settings.

Expected respondents include pharmacists and pharmacy technicians. Pharmacists are health-care professionals licensed to engage in pharmacy with duties including dispensing prescription drugs, monitoring drug interactions, administering vaccines, and counseling patients regarding the effects and proper usage of drugs and dietary supplements. Pharmacy technicians work closely with a pharmacist to ensure the health and safety of their patients. They locate, dispense, pack, and label a prescribed

medication for a patient that is then reviewed for accuracy by a pharmacist before dispensed to the patient. The assessment also allows for pharmacies to use third-party entities to complete the survey. Examples of third-party entities may include solution providers, wholesale distributors or consultants.

2. Procedures for the Collection of Information

As noted above, we have been working with both the APhA and the NCPA to spread awareness among their membership of the planned assessment to be completed by qualified pharmacies. These organizations have already offered to assist.

In addition, FDA will use our existing industry stakeholder email list to spread awareness of the assessment being available and post information on our website regarding the assessment. After the DSCSA Small Dispensers Assessment is launched, individuals representing small dispensers interested in participating will electronically submit their responses to the assessment questionnaire using a link provided on the following webpage, https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers. Survey responses will be anonymous and non-attributable. The results of the survey will be aggregated and not associated with any individual person.

3. Methods to Maximize Response Rates and Deal with Non-Response

The survey will be administered electronically using a link on FDA's website. To help ensure that the participation rate is as high as possible, FDA and the contractor will:

- Design a survey that minimizes burden (modest in length with clearly written questions).
- Administer the study over the internet, allowing respondents to answer questions at a time and location of their choosing.
- Send email notice regarding how to participate in the assessment using the existing Office of Compliance industry stakeholder email list.
- Work with both the American Pharmacists Association (APhA) and the National Community Pharmacists Association (NCPA) to spread awareness among their membership when and where the assessment is available to be completed by qualified pharmacies. These organizations have already offered to assist.

4. Test of Procedures or Methods to be Undertaken

Changes to the questions were considered after a first draft of the questions were made available for review by the public through a Federal Register Notice.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The contractor, CAITTA, and subcontractor, Light Pharma Inc., will collect and analyze the data on behalf of FDA as a task order under Contract # 75F40119D10017. G.K. Raju, Ph.D., and Reuben Domike, Ph.D., are the Project Directors for this project.

G.K. Raju: gk.raju@lightpharma.com
Reuben Domike: reuben.domike@lightpharma.com

Data analysis will be overseen by the Small Dispensers Assessment Workgroup members in CDER OC/ODSIR.