### United States Food and Drug Administration Generic Clearance: FDA Rapid Response Surveys OMB Control Number 0910-0500 Gen IC Request for Approval

FDA uses the Rapid Response Surveys to further develop tools and science necessary to better understand where vulnerabilities are and the most effective ways to minimize them, as well as to intervene and respond once a problem occurs.

Title of Gen IC: [Provide the name of the collection of information that is the subject of the request.]

#### 1. Statement of Need:

[Provide a brief description of the purpose of this collection.]

## 2. Intended Use of the Information:

[Indicate how the information will be used and if this is part of a larger study or effort.]

## 3. **Description of Respondents:**

[Describe participants/respondents.]

## 4. How the Information is Collected:

[Describe the method of collection and who (e.g., contractor) will conduct.]

# 5. Consistent with Currently Approved Supporting Statement

[Insert brief description and justification if there are any deviations to the described methods, procedures, and uses of data contained in the Rapid Response Survey 2017 version of the Supporting Statement.]

### 6. **Burden:** [Complete the table below.]

Burden Hour Computation -- Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours).

### Example:

Type/Category of Respondent	No. of Respondents	Participation Time	Burden
Patient interview	40	(minutes) 30/60 minutes	(hours) 20
Prescriber interview	10	30/60 minutes	5

# 7. Date(s) to be Conducted: [Insert date(s).]

8. **Requested Approval Date:** [Insert date.]

### 9. FDA Contacts:

Program Office Contact	FDA PRA Contact
[Insert name, phone number and center.]	

10. **CERTIFICATION:** In submitting this request, I certify the following to be true:

- a) The collections are voluntary;
- b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
- c) The collections are noncontroversial;
- d) Personally identifiable information (PII) is collected only to the extent necessary<sup>1</sup> and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.

<sup>&</sup>lt;sup>2</sup> As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."