FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

TITLE OF INFORMATION COLLECTION: Conducting Focus Groups & In Depth Interviews to Understand and Differentiate the Impact of REMS/ETASU on Prescriber Practices

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   FDA would like to explore ways in which Risk Evaluation and Mitigation Strategies (REMS) can be made more compatible with existing prescriber practices. To achieve this, FDA seeks to conduct focus groups and in-depth interviews with prescribers to better understand their practice settings, including the typical workflows, activities, and decision-making processes within each setting. In addition, FDA wishes to assess the extent to which Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) impact existing prescriber practices and impose burdens on prescribers.

   To this end, FDA is seeking OMB approval to conduct focus groups (and if needed in-depth interviews) to study participants' opinions of the burdens of prescribing medicines that are governed by REMS (risk evaluation and mitigation strategies) and learn the details and nuances of the prescriber settings and prescribing processes from those who work in settings were REMS are required.

   The sessions will help FDA understand the complexity of the setting dynamics and the extent to which a REMS impacts prescribing practices. They will also inform our understanding of prescribing processes to inform the development of process models (models describing and detailing the steps and decision points in the prescribing process).

2. **Intended use of information:**
   The FDA and Deloitte Team expects to use the findings from these focus groups and interviews to understand the dynamics of the prescriber setting and the extent to which a REMS impacts prescribing practices, while collecting process information for use in developing the process models. Specifically, the Deloitte Team will focus on verifying insights from an environmental scan and expert opinion (conducted earlier), as well as identifying and documenting those features of each setting that affect prescriber workflow and decision making. Of special importance in these sessions will be capturing the nuance and details not readily apparent in the environment, but acutely felt by practitioners and prescribers working there. The Deloitte Team will analyze all facilitated session data and prepare a summary of findings report complete with an initial understanding of the features and variance of features in each setting.

   The raw data for these reports will be the words, phrases, sentences, and non-verbal responses of the participants. The final report will be based on the discursive data gathered from each group. The report will detail the characteristics of each group and will highlight variations and commonalities between the groups. Because focus group research constitutes a qualitative methodology, quantitative results will not be reported.

FDA recognizes that the data collected will not be statistically representative of population segments characterized by the groups.

3. **Description of respondents:**
FDA contracted Deloitte Consulting LLP and Global Prairie (referred to as the Deloitte Team) to conduct these in-person focus groups.

Focus Groups/Interviews
For recruiting purposes, the Deloitte Team will construct a participant screening tool with selection criteria and work with physician networks, professional medical groups, and medical professionals to identify and screen potential participants.

Respondents will be recruited and screened for eligibility according to the criteria in the attached participant screener.

Respondents will be offered an incentive of up to $75 for their participation.

4. **Date(s) to be conducted and location(s):**
Pending OMB approval by [date requested], focus groups are planned for the following dates and locations.

[Dates and Locations TBD]

5. **How the Information is being collected:**
Members of the Deloitte Team will serve as moderators for all focus groups. Members of the FDA will be provided the opportunity to observe the sessions from observation rooms at Deloitte offices or FDA conference rooms. The focus group sessions will be audio-taped to ensure a verbatim record of the proceedings is captured.

Key research questions for the project are summarized below:
- What is the complexity of the setting dynamics?
- To what extent do REMS/ETASUs impact prescribing practices?
- What types of burden do the REMS/ETASUs drugs place on the prescriber/prescribers practice?

Each discussion will begin on or near the prearranged time. After short introductions, the moderator will ease the participants into a discussion of specific topics with a more general "warm-up" question. The moderator will not pose any questions of a sensitive or private nature. The moderator will continue to facilitate the discussion until all of the topics in the moderator guide have been addressed. The amount of time allowed will accommodate ideas and questions spontaneously generated from the discussion. Reliability and validity will be assessed iteratively within the discussions by revisiting participants' verbalizations and asking for clarification. This will be done both within the course of the individual sessions and between the separate sessions. The groups will be audio recorded. Written and electronic transcripts of the focus groups will be prepared from these recordings, with all personally identifying information removed. These transcripts will be used by the moderator to prepare a final report.

The Deloitte team and focus group facility will comply with safeguards for ensuring participant information is kept private to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to an individual.

6. **Number of focus groups:**
   Focus groups will not exceed 9 participants, and the number of focus group sessions will not exceed 12. The Deloitte Team will work with FDA staff to determine and prioritize the roster of participants and the composition of the groups.

   The groups will consist of Healthcare professionals who prescribe medications with REMS including ETASUs. This includes but is not limited to:
   - Physicians
   - Registered Nurses
   - Medical Assistants
   - Clinical Pharmacists
   - Administrative Staff

7. **Questions of a Sensitive Nature:**
   N/A

8. **Description of Statistical Methods (i.e. Sample Size & Method of Selection):**
   The Deloitte Team or facilities staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. We will recruit 12 participants for each session, to ensure a minimum of 9 participants show up for each session.

   The Deloitte Team and focus group facility will recruit approximately 144 individuals, expecting to have eight or nine participants per group. No more than nine participants will participate in a group, regardless of whether or not more than nine arrive as planned. Past experience has shown that this amount of over-recruitment generally ensures that enough participants will show up for the groups.

   The time required for screening and participation will be two hours per participant. There will be a total of no more than 9 participants in 12 groups, producing a conservative total estimated respondent burden of 216 hours (this estimate is additionally conservative).

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
General Public (healthcare professionals and non-healthcare	108	120 min/60 * 108 Participants	216

professionals)			

REQUESTED APPROVAL DATE: TBD

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