# FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF RAPID RESPONSE SURVEYS (0910-0500)

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 INFORMATION COLLECTION:** rapid interviews and survey of patients being treated with Ambien or Lunesta or their health care professionals.

## DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **What is the problem to be investigated:**

   FDA Drug Safety Communications that rapidly convey risk information to the public comprise some of the more important public health responsibilities of FDA's Center for Drug Evaluation and Research. The impact of the DSCs has never been fully studied scientifically. FDA's ability to react quickly and appropriately with effective public health communications to inform clinical decision-making depends upon effective communication of rapid and accurate assessment of the potential drug safety risk. FDA seeks to scientifically optimize communication to inform clinical decision-making by scientifically improving the effectiveness of Drug Safety Communications as mandated by the patient or consumer oriented directives of the FDA Safety and Innovations Act.

   As Drug Safety Communications are intended to inform the clinical decision-making event for patients who are in treatment with drugs (e.g., zolpidem or eszopliclone) with their prescribers to reduce the likelihood of unintended harm as a consequence of taking the medication. Hence, this study employs advanced scientific methods such as use of a scientifically designed random sampling frame to identify patients or their healthcare prescribers to be interviewed directly using a half hour semi-structured interview designed by expert social scientists in collaboration with FDA scientists to better understand the impact of the DSC. The information will be assessed qualitatively for thematic saturation of repetitive messages that patients and HCPs take away from the rapid FDA DSC messaging. The information on the impact the drug safety communications from the interview will be developed in a second phase of the study into survey items to assess quantitatively in the same population without the patients who were interviewed.

   The scientists conducting the interview phase of this study with patients actually being treated with Ambien or Lunesta sampled from a nationally representative insurance claims database are concurrently seeking rapid approvals for the interview with their institutional review boards (IRBs). The interview data will play an important role in understanding how FDA risk communications impact patients and their healthcare prescribers to optimize risk communications that will increase the safety of the drugs related to the DSCs while minimizing the potential risk being communicated. The result will be enhanced protection of public health.

2. **Please describe the method to obtain the convenience sample:**

This study uses a random sampling frame to identify patients and healthcare prescribers. The Optum scientific study team using the Optum database will construct a sampling frame from all new users of Ambien or Lunesta. The target population of the sample frame will include only

adults who are at least 18-89 years of age, medical and pharmacy coverage is required, at least 2 dispensings for zolpidem or eszoplicone between 01 July 2012 and 30 June 2013 ; must have had at least 6 months continuous enrollment prior to first study drug dispensing (either zolpidem or eszopiclone), and are in the commercially insured population with personal health information and personally identifiable information in the data source that will not be identifiable to the researchers. We will select a stratified random sample of 1,000 patients from all patients considered suitable for survey within our predetermined strata (drug, age, and new user status). Potential recruits will be invited on a rolling basis to reach the target numbers (40 patient interviews with 20 from the zolpidem population and 20 from the eszopiclone population).

Nielsen's division, Consumer Insights North America (formerly Harris Interactive), a firm with very extensive experience in the conduct of qualitative interviews, will manage the recruitment process with direct oversight from BWH investigators, Drs. Campbell and Kesselheim, and in partnership with their collaborator at Optum-Epidemiology. Under supervision of the BWH and its partners at Optum, the potential interview participants will be recruited by Nielsen. Optum will provide participant name and address to Nielsen. In turn Nielsen will print and mail study packets to potential participants. The mailing will be sent out in a personalized envelope (i.e., the address is printed directly on the envelope) and priority postage will be used. Personalized materials and priority postage have all been shown to increase response rates in mail surveys. Nielsen will send invitation packets to the sample of 1,000 patient participants. A reminder packet will be mailed at week 3 to all non-responders. The recruitment period will be up to 9 weeks long.

Study packets will contain the following: (1) an invitation letter that will describe the goals of the study, invite recipient to participate in a telephone interview, and provide instructions for participation; (2) the IRB-approved consent form with telephone number collection form; and (3) a postage-paid business reply envelope. The invitation letter will be printed on Optum and the health plan letterhead and signed by a representative of the health plan. A signed informed consent and receipt of a participant's telephone number will be required for study participation. We will use incentives to enhance recruitment: patients will be offered $50 for completing the interview. Response is entirely voluntary. (Please see Appendix I. Interview Script for Patients/Consumers).

Throughout the recruitment period, participants will be contacted after informed consent and telephone number are received. Nielsen will call the participants and conduct the interviews over the phone, according to the study protocol we provide. All participants who provide a completed informed consent form and telephone number during the recruitment period will be interviewed, even if the study's sample size goal has been met. Participants who respond after enrollment has closed will receive a letter thanking them for their interest in the study and inform them that study has closed.

The interviews of patients will be conducted by telephone by trained professional interview staff at Nielsen. Interviews are expected to be 30 minutes long. Nielsen will provide a skilled interviewer. Interviews will be audiotaped, with prior participant consent. After the interviews, Nielsen will transcribe both the recorded interview and redact any protected health information (PHI)/personal identification information (PII). Nielsen will deliver the redacted transcripts to BWH for coding and analysis. Upon completion of the telephone interview, Nielsen will send each participant a thank you letter and their incentive.

Prescribers may provide different insights into the accessibility, understanding, and implication of specific drug safety communications. We will therefore conduct a similar semi-structured interview of prescribers of drugs related to DSCs selected for this project (zolpidem and eszopiclone). We anticipate that 10 providers will be interviewed. The target population will be providers who have prescribed either zolpidem or eszopiclone in the past year. Optum will select a random sample from all providers considered eligible for the study. We intend to have an initial recruitment sample of 200 prescribers.

The inclusion criteria for selecting providers will include: A specialty related to primary care (internist, general practices, family medicine, obstetrics and gynecology); prescriber of either zolpidem or eszopiclone (including those who prescribed both) sometime between 01 July 2012 and 09 January 2013 as well as a prescriber of either zolpidem or eszopiclone (including those who prescribed both) sometime between 09 January 2013 and 30 June 2013. Prescribers will be excluded if they have no identifiable or valid mailing address available; provider listed on the Optum "do not contact" list or excluded by the health plan review for contact. Response is entirely voluntary will be asked for consent to participate.

The commercially-available data from this source (to be used for this study) represents adjudicated claims that have been further processed for usability and de-identified for assurance of patient confidentiality. No identifying information will be contained on the final data file sent to the FDA.

3. **Are there any deviations to the described methods, procedures, and uses of data contained in the Rapid Response Survey 2011 Justification Statement:**
   YES / NO (if no skip to #5)

   NO

4. **If yes, please describe:**

5. **Burden Chart and Description:**

   Based on testing of the brief questionnaire and extensive experience with telephone interviews of this type, it is anticipated that respondents will complete the interview in thirty or fewer minutes. The burden table below provides two estimates. The first row provides information on the 30 minute semi-structured interviews of 40 patient respondents who are dispensed zolpidem or eszopiclone. The second row includes the ten 30 minute semi-structured interviews of healthcare providers.

**BURDEN HOUR COMPUTATION**

| Type/Category of Respondent | No. of Respondents | Participation Time (minutes) | Burden (hours) |
|---|---|---|---|
| Patient interview | 40 | 0.50 (30 minutes) | 20 |
| Prescriber Interview | 10 | 0.5 (30 minutes) | 5 |

**Attach Questions**

Attached are the patient (Appendix I) and prescriber (Appendix II) telephone interview scripts. The patients are asked to answer eight questions. The prescribers are asked to answer 17 questions.

**REQUESTED APPROVAL DATE: November 3, 2014**

**NAME OF PRA ANALYST & PROGRAM CONTACT:**
**FDA: Ila S. Mizrachi**
**CDER: Gwen Zornberg**

**FDA CENTER:** Center for Drug Evaluation and Research