0910-0500
FDA's Rapid Response Survey
Summary of Survey Conducted

FDA's Center for Drug Evaluation and Research needed to use the FDA Rapid Response Generic Survey to conduct rapid response interviews and surveys of patients being treated with Ambien or Lunesta.

What was the problem to be investigated?

FDA's drug safety communications rapidly convey risk information to the public. 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. 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. The impact of the drug safety communications has never been fully studied scientifically. We chose this generic collection so the information could be collected extremely fast, as this was perceived to require additional information to determine if FDA intervention was required.

The method used to obtain the convenience sample.

The study used a random sampling frame to identify patients and healthcare prescribers. The Optum scientific study team using the Optum database constructed a sampling frame from all new users of Ambien or Lunesta. The target population of the sample frame included 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; 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. We selected 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 were 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). The interviews of patients were conducted by telephone by trained professional interview staff at Nielsen. Interviews are expected to be 30 minutes long. Interviews will be audiotaped, with prior participant consent.

Consumer Insights North America will manage the recruitment process with direct oversight from investigators and in partnership with their collaborator at Optum-Epidemiology. 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). (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.

Prescribers may provide different insights into the accessibility, understanding, and implication of specific drug safety communications. We therefore conducted 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.

Burden imposed.

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. The total estimated burden is approximately 25 hours.

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