FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF COMMUNICATION TESTING FOR DRUG PRODUCTS (0910-0695)

TITLE OF INFORMATION COLLECTION: Consumer and provider understanding of safety issues around online purchase of imported drugs

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   FDA is authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 393) to ensure the safety of foods and drugs. The practice of drug importation involves bringing drugs that are manufactured for sale outside of the United States (U.S.) into this country for use by U.S. consumers. Drug importation by individual consumers outside the legitimate supply chain (also known as personal importation), became a prominent issue in the early 2000's due to rising prices of prescription drugs and is illegal under the current law. As consumers searched for ways to obtain cheaper prices outside the normal process, the growing popularity and availability of the Internet provided a new way for consumers to obtain prescription drugs, both legally and illegally. FDA is concerned about the potential risk of consumer exposure to foreign substandard or potentially counterfeit versions of FDA-approved drugs. Concerns include exposure to dangerous or ineffective ingredients and to the consequences of drug manufacture under unsanitary conditions. These unapproved drugs may be manufactured in establishments that FDA does not inspect. They also have not gone through the rigorous FDA drug approval process that ensures the safety, efficacy, and integrity of the product.

   The specific purpose of this project is to provide FDA with key information on consumers' and healthcare professionals' existing perceptions and their decision-making about the risks of purchasing imported drugs on the Internet from non-verified sources. This key information would include the consumer and health care professional level of understanding of perceived differences between buying drugs through U.S. supply chain distribution channels versus purchasing those drugs online outside legitimate channels. FDA would also like to understand the factors that influence healthcare professionals' decisions about how to communicate with their patients about buying imported drugs over the Internet. The information obtained will be used to help FDA understand how to communicate strategically with consumers and healthcare professionals about the relative benefits and potential risks of buying imported drugs if a drug importation program were established.

2. **Intended use of information:**

   This project will synthesize current expert knowledge and the information collected in this data collection to develop an educational strategy to guide consumer and healthcare professionals' decision making around online drug purchases. The long-term objective is to reduce significantly the online purchase of counterfeit imported drugs.

3. **Description of respondents:**

   There are three groups of respondents, consisting of consumers and healthcare providers, who will be selected using the following criteria:

- Group 1: Consumers (n=100) who purchased prescription drugs on the Internet for their use in the past year; ineligible if employed in the pharmaceutical industry or employed in a position involving pharmaceuticals, or if a healthcare professional; roughly representative of the U.S. civilian, non-institutional population by age and sex. Each interviewee will be paid an incentive fee of $31.50 for their participation.

- Group 2: Physicians or nurse practitioners (n=40) who are licensed to prescribe drugs in the U.S. for chronic diseases (high blood pressure, hypercholesterolemia, heart disease), lifestyle drugs (erectile dysfunction, weight loss), drugs for terminal conditions (e.g., chemotherapy agents) or pain killers to patients; must be in primary patient care (i.e., internal medicine [including internal medicine physicians with specialties in, for example, cardiology, gastroenterology, or endocrinology], family medicine, obstetrics and gynecology, or general medicine) and have been in practice for no fewer than five (5) years; ineligible if employed in the pharmaceutical manufacturing industry or if employed in a position involving pharmaceuticals; physicians shall be sampled from the American Medical Association Master File List, which the Contractor shall purchase; roughly representative by age and sex of U.S. physicians or nurse practitioners. Each interviewee will be paid an incentive fee of $75 for their participation.

- Group 3: Physicians or nurse practitioners (n=9) employed by FDA and approved to and working in clinical practice, who are licensed to prescribe drugs in the U.S. for chronic diseases (high blood pressure, hypercholesterolemia, heart disease), lifestyle drugs (erectile dysfunction, weight loss), drugs for terminal conditions (e.g., chemotherapy agents) or pain killers to patients; must be in primary patient care (i.e., internal medicine [including internal medicine physicians with specialties in, for example, cardiology, gastroenterology, or endocrinology], family medicine, obstetrics and gynecology, or general medicine) for no fewer than five (5) years. These interviews will be conducted during working hours and are work-related (no incentive nor burden hour estimate is provided for this group).

4. **Date(s) to be Conducted:**

   June 4, 2012 – October 26, 2012

5. **How the Information is being collected:**

   For the consumer study, the contractor, RTI, will recruit both rural and urban subgroups. Since proximity to a local pharmacy is a variable of interest to the FDA, RTI will recruit some participants that live at least 15 miles from a pharmacy. RTI will also recruit participants that vary in terms of their insurance status (insured, uninsured) and whether they receive insurance drug subsidies (yes, no). Targeted area include locations in the North (e.g., Chicago or Boston), South (e.g., Atlanta, Houston, or Orlando), East (e.g., New Jersey or Philadelphia), and West (e.g., Los Angeles or Phoenix).

   Physician respondents for the group 2 prescriber interviews will be sampled from the American Medical Association Master File List, which RTI will purchase. If RTI is unable to recruit sufficient numbers of physicians, RTI will recruit nurse practitioners in select areas through the use of a site such as www.healthgrades.com. FDA will assist RTI with identifying group 3 interviewees and will provide RTI with their contact information.

RTI will coordinate with a recruitment firm to recruit interviewees for the consumer interviews and group 2 prescriber interviews, as needed, and to schedule the interviews. RTI will establish a subcontract with Schlesinger Associates or a similar marketing research firm with multiple national locations. All interviews will be conducted over the telephone by a two-person RTI team comprised of one interviewer and one note taker. The recruitment firm will screen potential participants, schedule the interviews, send them an initial packet of information on the study, and make reminder calls prior to the interviews.

The methodological approach is mental models research. In this research, the FDA prescribers (physicians and nurse practitioners) are identified as experts. The open-ended interview protocol for prescriber interviews is attached. These interviews will provide the *Expert Model* against which prescriber and consumer decision making will be evaluated.

6. **Confidentiality of Respondents:**

Information provided by respondents will be kept private and anonymous, except as otherwise required by law. This will be communicated to Interviewees by means of scripts read prior to telephone interviews. Interviewees also will be advised of: the nature of the activity; the purpose and use of the data collected; FDA sponsorship; and the fact that participation is voluntary at all times. Because responses are voluntary, Interviewees will be assured that there are no penalties for deciding not to respond, either to the information collection as a whole or to any particular questions.

Only personnel from RTI will have access to individual-level interview data. All contracted project staff conducting the information collection must take required measures to ensure the privacy and anonymity of data. Personally identifiable data shall be limited to information that may be required in the process of enrollment. Personally identifiable information will be accessible to only those contractor and subcontractor staff who need them and will not be linked to interview data. All personally identifiable data will be destroyed following interview data collection. Neither FDA employees nor any employee of any other Agency will have access to this information.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of educational materials. Raw data from data collections that include sensitive information will not be retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

Educational or communication efforts described in this proposal are typically considered exempt from the "Regulations for the Protection of Human Subjects" in accordance with paragraph (b)(3) of 45 CFR Sec. 46.101. Before data are collected, FDA researchers will obtain an exemption or a full approval for all research from FDA's IRB, the Research Involving Human Subjects Committee.

7. **Questions of a Sensitive Nature**

Some questions may touch upon purchase of drugs online which is an illegal activity. Interviewees will be assured that the information is voluntary and will be treated as private and anonymous, that they don't have to answer, and that the information will not be shared with FDA.

8. **Description of Statistical Methods**

The research approach to be used is known as *Mental Models*. The prescriber and consumer interviews are designed to address key topics identified in the *Expert Model* and allow for other topics to emerge through free expression. Structured qualitative analysis of the interviews against the *Expert Model* enables identification of the key areas of alignment and critical gaps in the thinking of consumers. The insight generated by such research directly supports the development of targeted educational strategies.

The transcribed interviews will be coded against the *Expert Model*. The contractor has a team of experienced coders and analysts who follow a standard set of coding and analysis procedures. Coded interviews will be transferred into a database. Qualitative analyses of the coded segments will assess detailed concepts and their relationships, identify emerging themes and identify any potential differences among the cohorts (consumers and prescribers). The contractor will conduct a qualitative analysis of gaps and alignments of Interviewees' mental models against the *Expert Model*, for example, by identifying emerging concepts or issues that were not previously identified in the *Expert Model*. The results of the research, aggregated across each research cohort will be presented in a written report of the results.

BURDEN HOUR COMPUTATION:

Respondent	No. of Respondents	Participation Time (hours)	Burden (hours)
U.S. prescribers	40	0:45	30
U.S. population	100	0:45	75
TOTAL			105

REQUESTED APPROVAL DATE: May 25, 2012

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