United States Food and Drug Administration

Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first two topic areas.

Because we recognize that the strength of data and the confidence in the robust nature of the findings is improved by utilizing the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm. The website includes links to the latest *Federal Register* notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a survey on direct-to-consumer advertisements conducted in 1999.

During the prescription drug approval process, sponsors propose proprietary names for their products. These names undergo a proprietary name review (PNR) that involves the Office of Drug Safety, the relevant medical office, and OPDP. OPDP reviews names to assess for alignment with the FD&C Act, which provides that labeling or advertising can misbrand a product if misleading representations are made (See 21 U.S.C. 321(n)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading. OPDP focuses its review on identifying names that overstate the efficacy or safety of the drug, expand drug indications, suggest superiority without substantiation, or are of a fanciful nature that misleadingly implies unique effectiveness or composition. While there are several ways proprietary names can be misleading, this research will primarily focus on overstatement of the efficacy of the drug product.

The proposed study is designed to provide systematic, empirical evidence to answer two research questions:

- Primary research question: How, if at all, do names that suggest the drug's indication affect consumers' and/or healthcare providers' perceptions of prescription drugs?
- Secondary research question: How, if at all, do names that suggest an overstatement of the efficacy of the drug affect consumers' and/or healthcare providers' perceptions of prescription drugs?

The ideas generated in the PDUFA pilot project proprietary name review concept paper of 2008[1] provided a starting point for the study. Based on ideas from that document, a review of the linguistics and social sciences literature, and an environmental scan, FDA developed and pretested an extreme, explicitly suggestive name (e.g., CureAll) and a neutral name for two indications, high cholesterol and gastroesophageal reflux disease (GERD; OMB Control No. 0910-0695). In the proposed main study, approximately 500 consumers from the general population and 500 healthcare professionals (including physicians, nurse practitioners, and physician assistants) will see these pretested extreme and neutral names plus five target (to be tested) names per indication and answer questions about the names, before and after they have been told what each drug's indication is. Target names will vary such that some efficacy implications are more apparent than others and some will more clearly imply indication or benefits than others. Dependent variables will include indication identification, efficacy, and perceptions.

2. Purpose and Use of the Information Collection

The purpose of this research is to provide information to inform FDA regarding healthcare provider and consumer interpretation of names similar to those proposed by industry. This knowledge will assist FDA in conducting the most relevant and efficient review of proprietary tradenames. Part of FDA's public health mission is to ensure the safe use of prescription drugs; therefore it is important to ensure that tradenames are not misleading.

[1] https://www.regulations.gov/docket?D=FDA-2008-N-0281

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. One hundred percent (100%) of participants will self-administer the survey via a computer, which will record responses and provide appropriate probes when needed. In addition to its use in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each participant, and by keeping the written parts of surveys to less than 20 minutes in both the pretests and main study.

4. Efforts to Identify Duplication and Use of Similar Information

To our knowledge, this study is the first to provide a systemic investigation of a variety of proprietary prescription drug names.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is one-time only. There are no plans for successive data collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of January 21, 2020 (85 FR 3392), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received seven submissions that were PRA-related. One submission was outside the scope of the research and is not addressed further. Within the remaining six submissions, FDA received multiple comments that the Agency has addressed below. For brevity, some public comments are paraphrased and therefore may not include the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: HCP = healthcare provider; FDA and Agency = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

(Comment 1) Two comments recommended that the study should exclude consumers who work in the healthcare, marketing, or branding industries; primary care providers that spend less than 50 percent of their time on patient care; and the Department of Health and Human Services employees.

(Response 1) We agree and currently have those exclusions included in the screener.

(Comment 2) Two comments recommended the screener should include additional inclusion/exclusion criteria, such as number of years in practice and in what size facility they work (HCPs), and whether consumers have any of five diagnoses and how many HCPs they see (consumers).

(Response 2) We plan to include most of the screening criteria and demographic data mentioned, including years in practice (HCPs); amount of time treating patients (HCPs); size of facility (HCPs); age (consumers); and diagnosis with one of the two illnesses which the hypothetical drugs in this study are indicated to treat--GERD and high cholesterol (consumers). Some of the other suggested questions for the screener are beyond the scope of this study. For this study, we have chosen to focus on primary care providers, as drugs for these two specific medical conditions are prescribed by primary care providers and should thus be salient for them. Additionally, we will ask relevant background questions of all participants, both HCPs and consumers, to determine age, gender, and race/ethnicity, as well as familiarity with the target conditions.

(Comment 3) One comment recommended that the complexity of the target names should be equivalent across indications.

(Response 3) We have attempted to make these as similar as possible, including having them reviewed by a linguist and checking the number of syllables across conditions.

(Comment 4) Three comments recommend better clarity around what the definitions of "typical" and "standard" and "extreme" and "neutral" mean when describing the fictitious drug name and how these categories were identified and validated.

(Response 4) The list of names was developed by a multimedia and creative services team that is well-versed in the practice of proprietary name development. The list was reviewed by the study team and also by a consultant with a Ph.D. in linguistics, who helped to screen for any overlap between categories.

In July 2019, we conducted a pretest of 120 healthcare providers and 121 consumers to establish the categories for these names. We combined results of four measures to determine the most extreme and most neutral amongst a list of names. These measures included ability to identify the medical condition for which the drug is indicated; perceived benefit and perceived balance of benefit and risk; and, finally, a ranking of most obvious benefit. Names with the lowest joint rank across the four measures were considered most extreme and those with highest were considered most neutral. The results were consistent between HCPs and consumers.

(Comment 5) One comment recommended excluding "extreme, explicitly suggestive" proprietary names that FDA would never permit or names that suggest the drug indication. The comment suggested instead that FDA use data that could assist the

Agency in determining impressions produced by permissible proprietary names and names that would marginally fail FDA's misbranding review.

(Response 5) The purpose of including "extreme" names in this study is not to have data on names that do not mimic real-world conditions, but to have something against which to compare the target names, which are similar to the kind of names that would be submitted to FDA for approval. Our findings may suggest that "extreme" and target names are very different and that target names are similar to more neutral names in their effects on perceptions.

(Comment 6) One comment inquired if FDA will be providing sound files with the intended pronunciation of each of the test names.

(Response 6) In consideration of this comment, and after hearing from our cognitive interview participants, we will introduce sound files at the beginning of the survey.

(Comment 7) One comment expressed concerns about how the selection of target names will represent the current landscape--that is, it questioned how FDA will generalize these study results across therapeutic areas not tested if only representing one or two therapeutic areas.

(Response 7) We recognize that our study is making use of only two therapeutic areas. As one research study, it cannot examine all possible therapeutic areas. Although our two divergent medical conditions will not provide us with unlimited information, they will provide limited generalizability and provide important information that may help inform the proprietary name review process.

(Comment 8) Two comments were concerned that the questionnaire would take longer than the estimated 20 minutes.

(Response 8) See our response to Comment 4 concerning the pretest that we conducted in July 2019. In the pretest, we successfully tested a total of 16 names across two indications in this time frame. During cognitive testing, we examined burden and decided to eliminate Q[uestion]7, which will speed response. We will also conduct a soft launch of the survey with approximately 10 percent of the sample and can look at actual length at that time. This gives us the ability to pause fielding of the survey and make further cuts if the soft launch data suggest it is necessary.

(Comment 9) Five comments recommended that we add "none of the above," "no impression," "no opinion" or "do not know" response options to some questions.

(Response 9) The rationale usually given for including "don't know"/"no opinion"/"none" options is to allow participants who cannot form a relevant judgment (e.g., due to insufficient information) a way to indicate as much. However, an unintended consequence of including these options is that they can facilitate satisficing, where participants who have enough information to form a relevant judgement

nonetheless choose “don’t know”/“no opinion”/“none” because it takes less effort. As a result, “don’t know”/“no opinion”/“none” options do not tend to improve measurement and tend to increase item nonresponse (i.e., missing data) (Ref. 1). For these reasons, we will not add these options.

(Comment 10) Seven comments suggested adding more open-ended responses to explain why respondents answered questions in certain ways.

(Response 10) As noted by two comments the survey may be longer than an average of 20 minutes, which will cause us to remove questions after cognitive testing. Unfortunately, it is impractical to include many open-ended questions in this particular research because of time constraints. Qualitative research on this topic may be a good idea for a future study.

(Comment 11) One comment recommended checks to ensure that respondents are not being careless in their responses (e.g., just guessing, providing random answers, straight-lining).

(Response 11) We intend to check for inattentive respondents by testing for straight-lining and examining the distribution of time to complete the study for outliers. Participants who complete the study plus or minus three standard deviations from the sample mean will be excluded from the main analysis. We agree with the recommendation to include speed traps/attention checks in the questionnaire and will add one to the study.

(Comment 12) Three comments requested access to the screener or study target names.

(Response 12) We have described the purpose of the study, the design, the population of interest, and have provided the questionnaire to numerous individuals upon request. Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise the research. We strive to publish the results of our research in peer-reviewed journals and all stimuli will be available at that time.

(Comment 13) One comment recommended a specific approach for addressing the issue of broadening the indication that included an unaided “fit to category” question and an open-ended “does the brand name tell you anything about the product?” OR “what does this name mean to you?”-type question for each name.

(Response 13) The approach described in this comment is one method to approach the issue of broadening the indication and may be useful for future research. However, in the current study we aim to collect information about multiple names, which precludes open-ended questions for each name in a single participant session. Moreover, our initial examination is focused on overstatement of efficacy. Broadening of the indication is another topic that researchers could pursue.

(Comment 14) One comment mentioned that we had no particular items on the issue of unique composition and suggested adding an open-ended question regarding general associations to determine whether a particular ingredient or dosage formulation is implied by a proprietary name.

(Response 14) Our current research is focused on the issue of overstatement of efficacy in proposed proprietary drug names. Future research could examine issues related to composition and dosage formulation, but that is beyond the scope of the current research.

(Comment 15) One comment suggested FDA should conduct two survey pretests: one to assess whether the survey answers the research questions, and one that allows respondents to complete the survey under the supervision of a moderator, who is able to converse with respondents and gather feedback on how participants interpret the questions. Further, the comment suggests FDA should consider conducting qualitative follow-up interviews with survey respondents to gain deeper insight into how the sample proprietary names affected their impressions of safety, efficacy and indication.

(Response 15) We have accomplished the goals recommended in this comment by conducting cognitive interviewing. During these cognitive interviews, participants were encouraged to think aloud as they reviewed and answered the survey with prompts from a trained moderator. These interviews enabled us to capture deeper, more qualitative responses from a small nonrepresentative sample of individuals in order to improve the questionnaire.

(Comment 16) One comment suggested FDA consider the inverse approach of our design by setting up the research to examine how, if at all, names that do suggest the drug's indication increase the chance for proper usage, reduce the potential for medication errors, do not mislead HCPs or patients regarding non-approved use of the drug, and increase the chance that if a patient does ask an HCP about a certain medication then that medication would be one approved to treat a condition with which the patient has been diagnosed.

(Response 16) The purpose of the current study is to provide evidence about whether certain types of names influence consumers' perceptions, as well as benefit and risk perceptions so that FDA reviewers may better assess names during premarket review. Other effects of names are beyond the scope of the current study but may be considered in future research.

(Comment 17) One comment suggested the ability of HCPs who prescribe drug products to determine whether a proprietary name overstates the efficacy of that product *without* the ability to review the respective package insert labeling fails to meet the intent of 21 U.S.C. 321(n). The comment further stated that OPDP and the sponsor of the product are in the best position to determine the relationship between the proprietary name and the material facts in the labeling of the product, which sometimes is not available at the investigational new drug (IND) application stage when proprietary names are developed and tested with consumers and HCPs.

(Response 17) The purpose of the current study is to determine whether a proprietary name itself could play a role in influencing consumer and HCP perceptions of drug risks or benefits by suggesting the medical condition for which the drug is indicated or by suggesting an overstatement of the efficacy of the drug. Including the package insert would confound any potential results of this study, as it would not be possible to tease apart whether perceptions were influenced by the name itself or the accompanying materials. We note that this is a large-scale study examining multiple names and that our purpose in conducting it differs from that of a pharmaceutical company engaged in developing and testing the proprietary name of one of its products.

(Comment 18) One comment suggested that the proposed primary research question, which is designed to determine how, if at all, a proprietary name that suggests the medical condition for which it is indicated affects perceptions of the drug, does not determine whether a name overstates the efficacy of the product.

(Response 18) We agree that whether a name suggests the medical condition for which a drug is indicated is a separate question from whether the name overstates the drug's efficacy. However, we aim, in part, to investigate how individuals perceive the efficacy of products when the names do suggest the medical condition they are indicated to treat. The purpose of this study is to compare names that: (1) with varying degrees of specificity, may suggest the medical condition for which a drug is indicated, with or without varied promises of effect (target names); (2) we know through pretesting overstate the efficacy (extreme names); and (3) we know to be neutral through pretesting. Perceptions of consumers and HCPs are important to consider when reviewing proprietary names and thus, important to test empirically.

(Comment 19) One comment suggested that research is not necessary because names should be evaluated by those who have medical and regulatory experience.

(Response 19) We agree that people who are knowledgeable about the relevant fields should make decisions about proprietary names based on the best information in their fields. Determining how names are processed and understood by consumers and HCPs is important information to be considered in the review of these names. Therefore, this research is being conducted to increase the body of evidence upon which experts can rely when assessing proposed proprietary names for misbranding concerns.

(Comment 20) Three comments mentioned the study sample size. One comment stated that the reason for selecting approximately 1000 respondents was not provided, and it suggested that the size of such a study on a proposed drug product would not be reasonable or cost effective for the pharmaceutical industry. One comment recommended that an appropriate sample size be used, and another comment remarked that the sample size seemed appropriate.

(Response 20) The sample size was selected based on power analysis. We have set statistical power for the main study to test five proposed names against both the neutral

control name and the extreme control name, using a 7 × 7 Latin square design. With a Bonferroni correction for up to 10 pairwise comparisons, the study is powered to detect conventionally small effects ($f \geq 0.06$, $dz \geq 0.21$, or 0.14 difference in proportions) assuming a family-wise alpha level of 0.005 and 90 percent power for all tests.

This is a large-scale study examining multiple names, whose purpose differs from that of one pharmaceutical company assessing their chosen names.

(Comment 21) One comment concurred that an automated online survey would be the most efficient means to conduct the research.

(Response 21) Thank you for this comment.

(Comment 22) One comment asked that we clarify what specific statistical tests will be performed to determine whether a particular target name has an improper (biasing) impact on perceptions of drug efficacy and/or safety--and (possibly) on other perceptions.

(Response 22) To compare names based on the categorical name recognition and perceived indication questions, we will apply nonparametric tests of dependent proportions. First, we plan to conduct Cochran's *Q* test separately for each list of names, testing whether the proportions of at least two names per list are significantly different from one another. We will follow up significant Cochran's *Q* tests with McNemar's pairwise tests, comparing each target name against the neutral and extreme names in each list.

To test for evidence of mean differences by drug name on interval-level outcomes (e.g., perceived efficacy magnitude, perceived severity of risks, and perceived balance of risks and benefits), we will use repeated-measures analyses of variance or mixed model analysis. We will run separate models for each list of names and study cohort. We will follow-up significant omnibus tests by conducting pairwise comparisons between each of the target names versus the neutral and extreme names.

See information about the study's statistical power assumptions above.

(Comment 23) One comment asked for clarity regarding what decision rule or norm/standard will be used to conclude that there is or is not improper suggestiveness.

(Response 23) There is an important distinction between investigating the effect of a prescription drug name on perceptions and establishing that the name is improperly suggestive. This study is focused on the effect on perceptions of: (1) names that suggest the medical condition for which a drug is indicated with varying degrees of explicitness and (2) names that suggest an overstatement of the efficacy of the drug with varying degrees of explicitness. Determining whether what a prescription drug name suggests or the name's degree of suggestiveness is "improper," or could contribute to misbranding the drug or to other violation(s) of the FD&C Act and Agency regulations, falls beyond the scope of the current project.

(Comment 24) One comment suggested clarifying the purpose and intended use of the data and further suggests that regardless of the purpose of the proposed information collection, in addressing use of the survey data, FDA should account for the First Amendment protection provided to proprietary names.

(Response 24) As stated in the 60-day notice, the purpose of this study is to expand the body of knowledge by answering questions about whether names alone impact consumer and provider perceptions of a drug. This information will help inform the proprietary name review process. FDA's review of proprietary names is conducted to help ensure that proposed proprietary names do not contribute to misbranding a drug or to other violation(s) of the FD&C Act and Agency regulations, particularly when that proprietary name appears in labeling (see, e.g., 21 U.S.C. 321(n) and 352(a)). We conduct our review of proprietary names in accordance with applicable legal authorities, including the First Amendment.

(Comment 25) One comment suggested Q1 should have a timer element (i.e., 15-20 seconds) for each set of seven names that will help to standardize the time spent by viewers on both sets and mitigate viewers who would quickly scan Set 1, only to spend more time on Set 2 after realizing they will be asked to recognize the names.

(Response 25) In addition to counterbalancing the sets of names, we will institute a time limit for each viewing.

(Comment 26) Another comment suggested that for Q1, we use names that were found unacceptable due to promotional reasons for foils.

(Response 26) The purpose of Q1 is to determine how well participants recall the names they viewed. The foils are used to help determine whether participants are merely checking off the complete list of names or marking ones they truly saw on the previous screen. Thus, we do not believe using actual names as foils would add value.

(Comment 27) One comment mentioned that Q3-Q7 introduce an aided portion of the survey (by grouping names into two specific medical conditions and identifying those names with each medical condition to the respondents) and suggested that, without seeing the product profile, "it will be difficult to get responsible data on efficacy perceptions of the respondents." Another comment suggested that Q3 should ask a more specific question, perhaps on unique effectiveness or overstatement of efficacy.

(Response 27) Our research questions focus on whether the names alone result in perceptions of risk or efficacy, thus, Q3-Q7 are directly relevant to the research questions. Regarding Q3, we do not want to lead participants into answers or confuse them by asking them about regulatory terms with which they are unfamiliar. We will delete Q7.

(Comment 28) Regarding Q2, one comment suggested caution in terms of handling responses in which respondents presented with a particular target name (e.g., "AltAFlux") fail to identify the indication that the name is hypothesized to be suggestive of (e.g., "Acid Reflux"), checking another indication instead (e.g., "Asthma"). In such cases, it would be inappropriate to interpret any observed effects on drug perceptions to the name being overly suggestive of a particular indication. A conservative course of action would therefore be to remove from subsequent analyses all instances in which a target name is not attributed to its hypothesized indication.

(Response 28) The target names are representative of the types of names that are frequently submitted to FDA for review. They may include information about the medical condition for which the drug is indicated, or both the medical condition and efficacy. We do not presuppose that a name's effect on perceptions of drug effectiveness are dependent on recognition of the medical condition for which the drug is indicated, though we will consider this mediation effect as we refine the analysis plan for this project.

(Comment 29) One comment suggested that Q4 does not seem relevant since serious side effects of the drug would normally be evaluated in the context of the clinical studies or post-marketing studies and would be presented in the package insert labeling.

(Response 29) The question is whether the name alone influences perception of risk and benefit; thus, Q4 is directly relevant to answering those questions.

(Comment 30) Three comments suggested deleting Q5. For example, one comment discussed that perceived balance of risks and benefits is usually communicated in advertising by utilizing the approved labeling in presenting fair balance and, thus, a proprietary name would not normally present risks and benefits. The comment stated that names that do present benefits within the name without context to its risk would not be considered misleading since the approved labeling would represent balance of risks and benefits.

(Response 30) Our research questions focus on whether the proprietary name alone affects consumer and HCP perceptions of risk or efficacy of the drug. Q5 helps to answer those research questions by asking participants to opine on whether the proprietary name alone indicates to them that the benefits of a product outweigh the risks. Our research will not answer the question whether a given name is misleading or whether labeling or advertising incorporating the name would violate the FD&C Act and its implementing regulations.

(Comment 31) One comment suggested that measuring attitudes toward each name (Q6) does not seem to add anything toward measuring the efficacy claims of a name and another comment recommends changing semantic differential endpoints for this item.

(Response 31) Measuring attitudes adds to our knowledge of how individuals interpret particular drug names. The semantic differential endpoints used in the original attitude

question, as well as the proposed replacements, are among those recommended by prominent attitude theorists (Ref. 2). We have used these items in several studies without any issues, including studies measuring consumer and physician attitudes toward prescription drugs. Nevertheless, we will replace the negative-positive item with an item using worthless-valuable as endpoints.

(Comment 32) Five comments suggested reducing or eliminating Q7, which questions participants about their attitudes toward the drug names.

(Response 32) As noted in Response 17, in the interest of reducing time burden for participants, we will delete this question.

(Comment 33) Two comments questioned the utility of or recommended deleting Q8.

(Response 33) We agree and will delete this item.

(Comment 34) Two comments suggested that Q9 and two comments suggested that Q10 and Q11 are not applicable to the objectives of this survey.

(Response 34) Similarity, typicality, and familiarity could reasonably influence perceptions of drug names independently of the experimental manipulation. These measures are being included in this study as potential covariates.

(Comment 35) One comment suggested that Q11 is confusing, as respondents are asked to rate if they "have heard of each of the following drug names before," after being previously told in the questionnaire introduction that the drugs "have been recently developed" and before being informed in the debriefing that the names are fictitious. Moreover, some respondents could interpret the present question as meaning "Were the following names mentioned in this survey?" which is presumably not the intent of the question.

(Response 35) We agree that this item as written was confusing, and this was confirmed by cognitive testing. Thus, we will alter the question to clarify that we are interested in whether respondents had heard the drug name prior to the study. This question will be used as a covariate in the study design.

External Reviewers

In addition to public comment, OPDP solicited peer-review comments from researchers in fields relevant to the communication of DTC prescription drug information. We received responses and incorporated the thoughts of the following individuals:

Lewis H. Glinert, Ph.D.
Professor
Linguistics Program
Dartmouth College
Hanover, NH 03755

Yeqing Bao, Ph.D.
Associate Dean of Graduate School
Associate Director of International Services
Professor of Marketing
SSB 218-I
University of Alabama in Huntsville
Huntsville, AL 35899

9. Explanation of Any Payment or Gift to Respondents

General population participants will receive panel points equivalent to $1.50. There is still no agreement on an "optimal" incentive amount. However, OMB has previously approved modest incentives for several FDA studies similar to this one. For example, OMB approved a $6.25 incentive for the Animation in Direct-to-Consumer Advertising, which included a 25-minute online survey using a non-probability panel (OMB Control No. 0910-0826). OMB has also approved $5 incentives for 20 minute online surveys using non-probability panels for the following projects: Disclosures in Professional and Consumer Prescription Drug Promotion (OMB Control No. 0910-0860); Character-Space-Limited Online Prescription Drug Communications (OMB Control No. 0910-0846); and Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion (OMB Control No. 0910-0849).

HCPs will receive honoraria in the amount of $50. Historically, physicians are one of the most difficult populations to survey, partly because of the demands on their professional time. Consequently, incentives assume an even greater importance with this group. In a survey of physicians, Gunn and Rhodes (1981; Ref. 3) found the response rate to an initial survey with no incentive was 58 percent, with a $25 incentive, 69 percent, and with a $50 incentive, 77 percent, with the difference between the $50 and the $25 incentive rate being statistically significant. Several studies (Refs. 4-8) have discussed the challenges of conducting HCP surveys and have concluded that offering substantial incentives is necessary to attain high response rates.

10. Assurance of Confidentiality Provided to Respondents

The contractor, RTI International, has designated IT Security and Privacy Offices to review and ensure compliance with current federal regulations, guidelines, and client requirements. RTI's network meets all National Institute of Standards and Technology confidentiality, integrity, and availability security standards, allowing RTI to provide appropriate security for the information. RTI complies with all ethical principles and

regulatory requirements involving human subjects research as specified in the Federal Regulations for the Protection of Human Subjects, 45 CFR Part 46.

All data will be collected with an assurance that participants' identity and personal demographic information will be held confidential and will not be used without their consent for reasons outside the scope of the research described. The consent form (Appendix E) contains a statement emphasizing that a participant's identity or personal information will not be linked to his or her responses and that participants can withdraw from the study at any time.

Contractors will not share personal information regarding participants with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court orders, or other legal processes. No personally identifiable information (PII) will be sent to FDA. All PII will be maintained by the independent contractor in a form that is separate from the data provided to FDA. The PII will be kept in a secured fashion that will not permit unauthorized access. Lightspeed Health already has PII such as names and contact information from people in its research database from which participants will be recruited. Lightspeed Health will not share the PII with RTI or FDA. There will be no link between the data collected and the participants' identities. FDA and RTI will not have the full names or any contact information for any of the participants.

For the main study, we will collect information about participant's consent to participate in the study, the measures included in the online survey, and demographic information about participants and nonparticipants based on the online panel profile account information. The data will be delivered by Lightspeed Health in a Statistical Package for the Social Sciences (SPSS) file. The data from the online survey will be stored on a secured, centralized database for data processing at Lightspeed Health. All data transfers of survey responses from participants' personal computers to the main servers pass through redundant firewalls. Additionally, information that is stored on servers is encrypted during back-ups, and the information is stored in a secured offsite location. Lightspeed Health will transmit the de-identified survey data to RTI via email. RTI will transmit the de-identified data to FDA via email as well.

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The complete list of questions is available in Appendix A.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

For both the pretests and main study, the questionnaire is expected to last no more than 20 minutes. This will be a one-time (rather than annual) collection of information.

FDA estimates the burden of this collection of information, including an additional 10% to account for recruitment issues, as follows:

Table 1. Estimated Annual Reporting Burden[1]

	No. of respondents	No. of responses per respondent	Total annual respondents	Average burden per response	Total hours
Consumer Screener	1,233	1	1,233	.08 (5 min)	98.64
HCP Screener	1,233	1	1,233	.08 (5 min)	98.64
Consumer Study	493	1	493	.33 (20 min)	162.69
HCP Study	493	1	493	.33 (20 min)	162.69
Total					522.66

[1]There are no capital costs and maintenance costs associated with this collection of information.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total contracted cost to the Federal Government for the collection of data is $469,684 ($117,421 per year for four years). This includes the costs paid to the contractors to develop the stimuli, program the study, draw the sample, collect the data, and create and analyze a database of the results. The contract was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not public information. The cost also includes FDA staff time to design and manage the study, to analyze the resultant data, and to draft a report ($58,000; 4 hours per week for four years).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for experimental data, such as descriptive statistics, analysis of variance, and regression models, will be used to analyze the data. See Part B for detailed information on the design, hypotheses, and analysis plan. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations at trade and academic conferences, publications, articles, and Internet posting.

Table 2. – Project Time Schedule

Task	**Estimated Number of Weeks after OMB Approval**
Pretest completed	20 weeks
Main study data collected	60 weeks
Final methods report completed	70 weeks
Final results report completed	90 weeks
Manuscript submitted for internal review	110 weeks
Manuscript submitted for peer-review journal publication	130 weeks

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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