

United States Food and Drug Administration

Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

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, in part, by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. 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, focusing 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 research data through analytical methodology development and investigation of sampling and response issues. This study will inform all three topic areas.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through 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 direct-to-consumer survey conducted in 1999. The present research involves assessment of how consumers and primary care physicians (PCPs) interpret terms and phrases commonly used in prescription drug promotion, as well

as those used to describe prescription drugs and prescription drug promotion more generally. This includes both what these terms and phrases mean to each population (e.g., definitions) and what these terms and phrases imply (e.g., about efficacy and safety). Some examples of interest include: “natural” or “naturally-occurring,” and “targeted” or “targeted therapy.” The full list for assessment will include approximately 30 terms and phrases for each population. To accommodate such a large number, presented terms and phrases will be accompanied by only limited context (terms within sentences and phrases within paragraphs, as opposed to full promotional materials). Understanding the most prevalent interpretations of these terms and phrases can help OPDP determine the impact of specific language in prescription drug promotion. For example, certain terms and phrases, when used without additional contextual information, might overstate the efficacy or minimize the risk of a product. Additionally, from a health literacy perspective, it is helpful to ascertain general understanding of such terms and phrases as this may aid in the development of best practices around communicating these concepts.

## 2. Purpose and Use of the Information Collection

The objective of this research is to provide an assessment of terms and phrases commonly used in prescription drug promotion, including what these terms and phrases mean to consumers and PCPs (e.g., definitions) and what these terms and phrases imply (e.g., about efficacy and safety). We will also assess terms and phrases used to describe prescription drug promotion. The results from this research will be used by FDA to inform its understanding of direct-to-consumer (DTC) and physician-directed promotion, inform regulatory policy, and may also help to identify areas for further research.

## 3. Use of Improved Information Technology and Burden Reduction

Burden will be reduced by recording data on a one-time basis for each respondent, and by keeping study procedures to 20 minutes for the Phase 2 surveys and to 60 minutes for the Phase 1 interviews. The Phase 2 consumer sample will self-administer the survey instrument via a computer and the Phase 2 PCP sample will self-administer the survey via a printed, mailed survey, an approach that has been tailored based on each population’s expected likelihood to respond. Administration of Phase 1 requires interviewing and thus will not involve self-administration of the survey. In addition to its use in data collection, automated technology will be used in data reduction and analysis.

## 4. Efforts to Identify Duplication and Use of Similar Information

We conducted a literature search to identify duplication and use of similar information. We conducted a review of the scientific literature by locating relevant articles through keyword searches using popular databases such as PubMed and PsycInfo. We also identified relevant articles from the reference list of articles found through keyword searches. We did not find duplicative work on the present topic.

## 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 November 6, 2019 (84 FR 59833), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received eight comments, but only five submissions were PRA-related. Within those submissions, FDA received multiple comments that the Agency has addressed.

(Comment 1): Four comments supported the proposed research as an important step towards addressing current issues with the United States' prescription drug advertisement practices.

(Response): FDA agrees with these comments to the extent they relate to this study.

(Comment 2): Two comments suggested the proposed research methodology could be improved by providing the general population with the option to complete the survey in writing or over the phone. These comments asserted that elderly consumers are highly susceptible to false and misleading advertisements of prescription drugs, and that elderly consumers use prescription drugs at rates higher than any other age group. The comments also indicated that elderly populations may face barriers to accessing a web-based platform to complete the survey.

(Response): While we agree that web panel surveys can sometimes have less than ideal coverage of populations like older adults, the survey proposed here would not be sampling from a web panel, but would instead use a probability sample selected from an address-based sample (ABS) frame to ensure a nationally-representative sample. This helps to ensure better coverage of older adults, who may be less likely to be part of an existing opt-in survey panel or less likely to answer a web-based ad to complete a survey than to respond to a mailed survey invitation. Pew research finds that 73% of people aged 65+ have access to the Internet in their home compared to 90% for the overall U.S. population.<sup>1</sup> To address this coverage concern, responses from older adults will be weighted to the full U.S. population.

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<sup>1</sup>Internet/Broadband Fact Sheet (2019). Pew Research Center. Retrieved from <https://www.pewresearch.org/internet/fact-sheet/internet-broadband>.

Our recent experience suggests we will be able to adequately represent this group. As an example, in a survey conducted by RTI on the Residential Energy Consumption Survey National Pilot, an analysis of representativeness among survey protocols found that for the older age group, web was less representative than a mixed mode survey allowing for either web-based or paper survey, but was still considered to have “good” agreement with the American Community Survey (considered the gold standard for U.S. demographic data).

(Comment 3): The comment indicated the proposed research methodology could be improved by including behavior-based questions in the surveys.

(Response): We agree about the value of measuring behavioral intentions in general. However, in this particular study, in which we are asking about a variety of terms and phrases used in prescription drug advertising that may or may not be relevant to all members of the sample, behavioral intention questions would not be appropriate. The drugs in question would not be relevant or salient for all consumers in the study. For example, a respondent will be able to answer questions about language used to describe migraine medication (e.g., #1 prescribed medication) even if they do not suffer from migraines. However, it would not make sense to ask them about their behavioral intentions related to taking that migraine medicine if they do not suffer from migraines. Given the limitations of space and scope, we do not plan to add more behavioral intentions measures into this study.

(Comment 4): The comment suggested that some of the longer contextual-based passages interviewees are presented with should include situations in which viewers/listeners are presented with previously seldom-used or new-to-the-public terms and phrases and an attempt at definition or generation of emotional valence by marketers.

(Response): The purpose of this study is for FDA to test understanding of terms “commonly used in prescription drug promotion.” Thus, those that have been “previously seldom-used” or are “new-to the-public” are outside the scope of the study and are not included in the survey materials.

The idea to study emotional valence is very interesting, but also beyond the scope of the current research.

(Comment 5): The comment included a note on the PCP mail surveys: rather than focusing on incentivizing response via an object included with the PCP mail surveys, the comment suggested that research funds would be better spent ensuring the surveys are engaging, easily understood by the two target audiences, short to complete, and presented with a clear deadline.

(Response): We believe we have the capacity both to incentivize the response and to ensure the surveys are engaging. For example, we specifically designed the advance mailings (letters that will go to potential participants) to follow best practices for ensuring the study is engaging, such as stating the purpose and likely outcomes of the research in the letter and including a graphic to identify the study on the postcard or envelope.

Token incentives have been shown in the literature to have a real impact on response rates, and increased response rates can save costs and potentially reduce nonresponse bias (if reluctant respondents are different from non-reluctant respondents). In fact, the literature has shown that even with short, engaging surveys, these types of token incentives can substantially boost response rates (Refs. 10-12).

(Comment 6): The comment suggested that the study population of healthcare providers should be expanded to include specialists.

(Response): While we understand that some of the topics may be relevant for specialists, and we do often include specialists in our research, our focus in the present research is on PCPs. Specialists are not as numerous as PCPs, which makes them harder to recruit. In 2018, for example, the proportion of specialists representing each specialty area ranged from 2% (endocrinologists) to 11% (psychiatrists and emergency medicine specialists).<sup>2</sup> These data demonstrate that the pool of potentially eligible specialists is limited. Given the large required sample size for this study, we chose to limit the population to PCPs.

(Comment 7): The comment suggested that FDA should use additional context for certain terms to more accurately represent the way in which these terms are conveyed in promotion. Specifically, the comment requested that FDA add context for the following terms:

1. HCP assessment term of “significant (as in statistically significant)”: The comment stated that this term should be accompanied by a 95% CI, hazard ratio and p-value as additional data points.
2. HCP and consumer assessment phrases “manageable safety profile; established safety profile; well-studied safety profile; “well-tolerated”: The comment stated that these phrases should be accompanied by an example, such as a table showing most common adverse events.

(Response): Regarding the term “significant (as in statistically significant)” and the suggestion to add additional data points: Although references to statistical significance in the prescription drug promotion marketplace are sometimes accompanied by other statistical information, at other times they are not. In this assessment, we wish to assess understanding of this phrase on its own.

Regarding “manageable safety profile” and related phrases and the suggestion to add an example such as a table showing most common adverse events: Given the length of the current instruments, we are limited in what can be included. The scope of this study includes terms and phrases and not graphics or numbers. However, we recognize the importance of studying those features as well. Examples of research involving these features can be found on the OPDP research website, linked earlier in this document.

(Comment 8): The comment suggests that the following commonly used terms should be added to the assessment to increase the utility, quality and clarity of the information collected.

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<sup>2</sup>Kaiser Family Foundation. (2018). Professionally Active Specialist Physicians by Field. Retrieved from <https://www.kff.org/other/state-indicator/physicians-by-specialty-area>.

For consumers and HCP, the comment suggested adding:

- a. “Potent” to assessment term “powerful;” and
- b. New assessment term “convenient/straightforward/simple/easy/easy to use.”

For HCPs only, the comment suggested adding “high affinity.”

(Response): Thank you for these suggestions. We added “potent,” “convenient,” “straightforward,” “simple,” “easy,” and “easy to use” to the surveys. For “high affinity,” we have conducted several informal searches, but have not found sufficient examples of the use of this term in promotional materials.

(Comment 9): The comment noted that the surveys take terms and phrases out of context and suggests that FDA should study how consumers and PCPs interpret representative promotional pieces that include appropriate accompanying context.

(Response): This study is one in a program of related research conducted by OPDP. In several related studies, we examine how consumers and PCPs interpret the terms and phrases in representative promotional pieces that include accompanying context. In contrast to this prior research, the proposed research allows for assessment of a large number of terms and phrases—effectively emphasizing breadth over depth, and involving data collection from a nationally representative sample. We believe these various approaches to studying language commonly used in prescription drug promotion complement one another and together contribute to a more comprehensive understanding of the research questions.

(Comment 10): The comment suggested that questions in the surveys may be leading. In describing the proposed research, the 60-day notice stated, “For example, certain terms and phrases, when used without additional contextual information, might overstate the efficacy and minimize the risk of a product.” The comment stated that this statement shows bias that manifests in the proposed questions and suggests that because the evident bias is deeply rooted in this proposed study and its surveys, FDA should fundamentally reformulate the proposed collection of information in its entirety.

(Response): We agree that some of the probes proposed for use in the Phase 1 research may appear to be leading, so we have rewritten these probes. For example, where it said “safer,” we have altered language to “more” or “less” safe.

In the Phase 2 surveys, the safety and efficacy questions are not leading or one-sided. The questions use bipolar response scales allowing respondents to indicate that the products using that term are less safe/effective, equally as safe/effective, or more safe/effective.

(Comment 11): The comment suggested that the proposed answers in the closed-ended surveys are unbalanced.

(Response): We have reviewed the Phase 2 questions and made some edits to ensure more balance.

It is important to note that the response options shown for many of the questions are just examples. The full list of response options used in the Phase 2 surveys will be developed based on responses to the Phase 1 interviews. As a result, the Phase 2 response options may skew slightly negative or positive depending on what interview respondents say in the Phase 1 interviews. However, we will ensure that there is balance with both negative and positive response options.

(Comment 12): The comment suggested that by asking respondents to compare closely related terms and phrases, the survey may force artificial findings of difference... The comment stated that even if the measured differences are real (and not due to biases in the surveys), it is unclear how the results would have any practical utility because there may not be any objective definitions of the terms with which to compare the results.

(Response): We describe below the process to mitigate the effects of this concern.

If participants in the Phase 1 research do not articulate differences between certain terms, we will exclude those terms from Phase 2. This will reduce the chance to find artificial differences between terms.

We can also split question sets into multiple individual questions. We will make decisions surrounding this solution following completion of the Phase 1 interviews.

For the consumer survey, which will be conducted online only, we will randomize the order in which the terms are presented. This will not eliminate context effects but will randomly distribute any error across terms rather than significantly biasing an individual term.

(Comment 13): The comment opined that the surveys, at least in the past, are unnecessarily duplicative of information otherwise reasonably accessible to FDA (e.g., focus groups conducted by FDA in 2014; and information available from third-party sources regarding the terms “many,” “most,” “majority,” “some,” and “few”).

(Response): We believe the research is not duplicative of that conducted in 2014 by FDA, but instead builds on that research. It is being conducted by the same research team and is part of a coherent program of research that includes formative focus groups, in-depth interviews, a survey, and an experimental study. We used those focus group reports to inform the development of answer options for this study. The very few terms that are repeated in the current survey have been included in the current study because researchers wanted to follow up on previous findings with a larger, nationally representative sample. Furthermore, that study did not collect any quantitative data on the terms.

Literature searches in multiple medical, social science and linguistics databases, including Pubmed, Web of Science, EBSCO Discovery Service, and Linguistics Database for research on how people quantify or interpret terms like “few” and “many” as we do in the present research did not reveal significant literature on these terms. It is important for FDA to understand how these terms are interpreted in the context of prescription drug promotion, thus we plan to keep them in the current study.

(Comment 14): One comment recommended that FDA remove questions about the terms “off-label” and “prescription drug promotion” as they are not terms used in promotion.

(Response): While “off label” and “prescription drug promotion” are not terms that are typically used in promotion, it is important for FDA to understand how healthcare providers perceive these terms in general. We have revised the description of the scope in the *Federal Register* notice to clarify this broader purpose. We now state: “The present research involves assessment of how consumers and primary care physicians (PCPs) interpret terms and phrases commonly used in prescription drug promotion, as well as those used to describe prescription drugs and prescription drug promotion more generally.”

(Comment 15): One comment recommended that FDA change the framing for the survey from a focus on “words or phrases that are commonly used in prescription drug advertising” to “words or phrases that are commonly used to describe prescription drugs.” The comment suggested that if the survey keeps the former, respondents will view the surveys through whatever biases they have for drug advertising.

(Response): Because it is our intention to examine what participants think in the context of prescription drug advertising, we have retained our original approach to framing the research, while also expanding that framing to reference terms or phrases that are commonly used to describe prescription drug promotion.

### **External Reviewers**

In addition to the comments above, the following experts reviewed the study design, methodology, and questionnaires:

1. Terry Davis, Ph.D., Professor of Medicine and Pediatrics, Feist Weiller Cancer Center, Louisiana State University Health Science Center
2. Michael Mackert, Ph.D., Professor, Department of Advertising, University of Texas
3. Rima Rudd, Senior Lecturer on Health Literacy, Education, and Policy, Harvard T.H. Chan School of Public Health

### 9. Explanation of Any Payment or Gift to Respondents

For completing the Phase 1 interview, consumers will receive \$75 and PCPs will receive \$225. For the Phase 2 survey, consumers will receive a \$5 prepaid cash incentive with the survey invitation, plus a \$20 postpaid incentive for completing the survey; and PCPs will receive a \$50 prepaid incentive exclusively. Based on our experience, and recent consultation with recruiting firms, these incentives are close to current market rates for each population and should help ensure high participation and show rates.

We also plan to embed an experiment in the PCP mail survey to assess the effect of token incentives on response rates. More information about this experiment is provided In Part B of this Supporting Statement.

Numerous empirical studies have established that incentives can significantly increase participation rates.<sup>3,4</sup> Incentives are intended to recognize the time burden placed on participants, encourage their cooperation, and convey appreciation for their contributions to the research. Incentives help ensure that sufficient numbers of respondents can be recruited to participate in the data collection. If we are unable to recruit sufficient numbers of respondents to participate in the data collection, the quality of the data will be compromised. Further, without the incentive as an inducement, it is likely that more people would need to be screened to achieve the desired cooperation rate, thus increasing the burden hours.

#### 10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information (PII) will be sent to FDA. Data from completed surveys will be compiled into an SPSS data set by RTI International, the contractor, with no PII for analysis. All information that can identify individual respondents will be maintained in a form that is separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. Confidentiality of the information submitted is protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). These methods will all be approved by FDA's Institutional Review Board prior to collecting any information.

For the interviews, only first names will be used when livestreaming and audio-taping participants, and transcripts sent to the FDA will not contain participants' names. Livestreaming of the interviews will not involve participants' faces and will only involve their verbal responses to the questions.

All participants will be assured that the information will be used only for research purposes and will be kept private to the extent allowable by law. The study instructions and informed consent will include information explaining to respondents that their information will be kept confidential. Participants will be assured that their answers to screener and survey questions will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Participants will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

All electronic data will be maintained in a manner consistent with DHHS's ADP Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

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3Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*.  
4Greenbaum, T. L. (2000). *Moderating focus groups: A practical guide for group facilitation*. Thousand Oaks, CA: Sage Publications, Inc.

11. Justification for Sensitive Questions

This data collection will not include sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
<i>General Population</i>					
Phase 1: Screener completes (assumes 35% eligible)	85	1	85	0.083 (5 minutes)	7
Phase 1: Number of completes	30	1	30	1	30
Phase 2: Screener completes (assumes 90% eligible)	1,185	1	1,185	0.083 (5 minutes)	98
Phase 2: Number of completes	1,067	1	$1,067 + 10\%^2 = 1,174$	0.333 (20 minutes)	391
<i>PCP Population</i>					
Phase 1: Screener	104	1	104	0.083	9

completes (assumes 30% eligible)				(5 minutes)	
Phase 1: Number of completes	30	1	30	1	30
Phase 2: Screener completes (assumes 90% eligible)	1,180	1	1,180	0.083 (5 minutes)	98
Phase 2: Number of completes	1,062	1	$1,062 + 10\% \text{ }^2$ =1,168	0.333 (20 minutes)	389
Total					1,052

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for both samples in the study.

### 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 estimated cost to the Federal Government for the research is \$658,901.00. This includes the costs paid to the contractor to assist with study design, questionnaire, and stimuli development, recruit a sample, collect and analyze data, write reports of work completed, and present findings. The task order 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.

1168

### 15. Explanation for Programs Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques, 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 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 posting on FDA's website.

Table 2.--Estimated Project Timetable

<b>Task</b>	<b>Estimated Completion Date</b>
FDA IRB review	July, 2020
30-day FRN publication	September 18, 2020
OMB Review of PRA package	September, 2020
Pretesting	November, 2020
Main Study Data Collection	March, 2022

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.