TITLE OF INFORMATION COLLECTION: Endorsement in Direct-to-Consumer Promotion: Cognitive Interviews

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

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 FD&C Act provides that labeling or advertising can misbrand a product if misleading representations are made (See 21 U.S.C. 321(n)). The FD&C Act also provides that a drug is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 352(a)).

Advertisers have used celebrity endorsers for years, and direct-to-consumer pharmaceutical promotion is no different, beginning with Joan Lunden's endorsement of Claritin in a 1998 DTC seasonal allergy campaign. As researchers studied the influence of celebrity endorsers, they theorized that a correspondence bias occurs in which people believe the endorser truly believes what they are saying. LaTour and Smith (1986)[1] examined whether a pharmacist, physician, celebrity, or consumer would be most persuasive in advertisements for four different types of OTC products. They found that physicians and pharmacists were the most likely to lead to purchase intentions, followed by consumers, and lastly, by celebrities. There were no differences among types of OTC product. Bhutada and Rollins (2015)[2] recently completed a study examining the role of endorser type (i.e., celebrity vs. expert vs. non-celebrity), and endorser and consumer gender in product DTC ads. They found, like LaTour and Smith (1986), that expert endorsers were thought of as higher in credibility and generally resulted in the same amount of attention as celebrities. The authors did not find that these endorsers resulted in greater intentions to seek out the drug product.

We propose to extend previous research by examining four types of endorsers in two separate experimental studies (Study 1: celebrity, physician, or patient endorser in print ad; Study 2: patient or influencer[3] endorser in Instagram post) and examining whether the presence of a disclosure of their payment status influences participant reactions. We propose to also test two different types of disclosure language—one direct and more consumer-friendly, and one less direct. **The first step of this process is to conduct**

1 LaTour, C., & Smoth, M. (1986). *Journal of Pharmaceutical Marketing and Management, 1(2)*, 117-128.
2 Bhutada, N.S., & Rollins, B.L. (2015). Disease-specific direct-to-consumer advertising of pharmaceuticals: An examination of endorser type and gender effects on consumers' attitudes and behaviors. *Research in Social Administrative Pharmacy, 11(6)*, 891-900.
3 "Influencer" is a "regular" person who has gained a following on a blog, a Twitter feed, or other social media medium.

cognitive interviews to improve the development of the questionnaires and the stimuli that will be used in the quantitative studies. That is the purpose of this current generic clearance request.

2. **Intended use of information:**

The results of this research will help us improve the quality and usefulness of the questionnaires and mock ads used in two subsequent experimental studies. The research described in this generic clearance will not be used beyond this purpose.

3. **Description of respondents:**

a. Disposition of groups from which the Contractor shall recruit participants

Participants for the cognitive testing will be sampled from the Washington, DC metropolitan area. As Study 1 will involve a fictitious drug for acne, adults aged 18 or over will be eligible for participation in the Study 1 cognitive interviews. Study 1 participants will be prescreened to ensure they are familiar with the celebrity used in the study. Since Study 2 will be testing a fictitious drug for endometriosis, only females aged 18 or over will be eligible for Study 2 cognitive interviews. For Study 2, participants will be asked questions about their familiarity with the web influencer used in the study stimuli, but do not have to be familiar with the web influencer to qualify for the cognitive interview. They must, however, be regular users of Instagram, meaning they use it at least on a weekly basis, in order to qualify for Study 2.

A mix of demographic characteristics will be achieved to ensure participants vary by race and level of education. All participants will be screened to ensure they can read and speak English. We will exclude individuals who work for the Department of Health and Human Services, a pharmaceutical company, an advertising agency, or a market research company. To avoid so-called “professional participants,” we will also exclude those who have taken part in focus groups or cognitive interviews in the past 6 months.

b. Sampling procedure

In order to guarantee two waves of 10 completed interviews, 26 participants (13 per wave) will be recruited from the Washington, DC, metropolitan area. Westat will recruit respondents using a convenience sample resulting from participants who respond to a post on a public message board (e.g., Craigslist). If the public message board ads do not yield enough participants necessary for the testing, Westat will supplement their efforts using a combination of recruitment methods including social media and Westat’s internal intranet system. Westat employees will not be eligible to participate.

c. Recruitment procedures

Potential respondents will be asked to complete an online screener to determine eligibility. Those who are eligible to participate will be contacted by a Westat recruiter who will schedule a convenient time for the interview. Participants will receive reminder emails and phone calls prior to the interview.

4. **Date(s) to be conducted and location(s):**

We plan to collect data between October and December of 2019, depending on date of OMB and FDA IRB approval. The interviews will be conducted at Westat's cognitive and usability testing laboratory located in Rockville, MD.

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

Cognitive testing allows us to study how participants understand, mentally process, and respond to the stimuli materials and survey questions. In doing so, we will be able to align the stimuli and questionnaires with the research questions and measurement goals, reduce measurement error, and reduce respondent burden, which will improve data quality, and reduce nonresponse. Cognitive testing is conducted through a process of in-person, one-on-one interviews.

Westat, on behalf of FDA, will conduct a total of 20 in-person cognitive interviews in two waves (10 interviews per wave). This methodology reflects current best practices, allowing revision from the first wave to be evaluated in the second wave.[4] Each wave of interviews will be conducted within a 2- to 3-day period to allow observation by FDA. During the interviews, trained qualitative researchers will show participants two versions of the stimuli, administer the questionnaire, and probe as needed to assess the comprehension, clarity, and completeness of both the stimuli and questionnaires. Each interview will last 60-minutes and will be audio recorded.

6. **Confidentiality of Respondents:**

Personally identifiable information (PII), including names and contact information (phone number and/or email address), will be collected by Westat recruiters for the purpose of scheduling eligible participants for interviews. These data will be securely stored in password-protected files to which only project staff will have access, and will be destroyed within a year of the end of the study. Names provided by adult participants on consent and incentive receipt forms will be stored in locked cabinets, separate from data. Westat will create a unique respondent ID number for each participant and develop a crosswalk linking the respondent ID to participant names and other PII. Only the Westat staff working on this project will have access to the crosswalk, which will be stored in a secure, password-protected file. Participant PII will never be associated with data collected during the interview. PII for individuals not selected for interviews will be destroyed immediately. PII for selected participants, including audio recordings, will be destroyed within a year of the end of the study.

To further protect respondent confidentiality, no names will be recorded on the interview notes or reported in any reports. Respondents will be informed that their name will not be linked to any of their responses, though we may include quotes that they provide in our reports. No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained by the independent contractor 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. The privacy of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA)

4 Willis, G. B. (2015). *Analysis of the cognitive interview in questionnaire design*. New York, NY: Oxford University Press.

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).

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' 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).

7. **Amount and justification for any proposed incentive:**

Offering an incentive is critical to ensuring that the sample recruited for cognitive interviews is not practiced volunteers or those with academic curiosity, who might differ from the average respondent we hope to attract in the main studies.[5] We propose an incentive of $50 for a 60-minute, in-person cognitive interview to ensure that we are able to attract a reasonable cross section of participants within the desired criteria and demographic characteristics (e.g., age, race/ethnicity, education). We are conducting cognitive interviews in order to ensure the effectiveness of the stimuli and survey question items before large scale fielding. Therefore, the minimal cost of the cognitive interview incentives will help ensure that when the stimuli and survey are fielded on a large scale that they yield high-quality data thus keeping the overall costs of the study to a minimum.

Recent studies on incentives show positive willingness to participate in qualitative research when an incentive is $50, compared with lower amounts.[6] Similar amounts have also been previously approved for cognitive testing in other studies fielded by FDA (e.g., *Food Safety, Health and Diet Survey* [OMB No.: 0910-0345], *Naloxone Cognitive Interviews to Optimize the Drug Facts Label* [OMB No.: 0910-0695]). Moreover, our own experience in conducting cognitive testing research indicates that offering nonmonetary incentives or an incentive that is below the commonly accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment;
- Increased likelihood of "no-shows" (which may result in methodologically unsound cognitive interviews).

Our proposed incentive amount will help ensure that participants honor their commitment of participating in the cognitive interviews. Incentives are based on (1) estimated average hourly wage for 1 hour, which is approximately $28[7]; (2) estimated time spent on an

5 Willis, G. (2015). *Cognitive interviewing: A tool for improving questionnaire design.* Thousand Oaks, CA: Sage.
6 Kelly, B., et al. (2017). What affects people's willingness to participate in qualitative research? An experimental comparison of five incentives. *Field Research, 29*(4), 333-350.
7 The average hourly wage according to the Bureau for Labor Statistics, for all employees on private non-farm

average driving commute to and from the Washington DC metro-located facility of approximately $28[8]; and (3) our contractor's and other researchers' experiences with using nonmonetary incentives, which generally produce participation rates no better than the complete absence of any incentives.[9]

8. **Questions of a Sensitive Nature:**

   None.

9. **Description of Statistical Methods (i.e. Sample Size & Method of Selection):**

   No statistical methods will be used.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Estimated Reporting Burden

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)	Total Hours
Number to complete the screener	50	1	50	.08 (5 min.)	4
Number to complete the study (included in number to complete screener)	20	1	20	1 (60 min.)	20
Total					24

REQUESTED APPROVAL DATE: October, 2019

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payrolls, in June of 2019 was $27.90. This data is reported at https://www.bls.gov/news.release/empsit.t19.htm, accessed 7/15/19

8 Assumes travel by automobile; calculation derived from average one-way travel time in the Washington, DC Metropolitan area multiplied by the BLS average hourly wage. https://www.census.gov/newsroom/press-releases/2017/acs-5yr.html, accessed 7/15/19.

9 See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly, 57*, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. *Maternal and child health journal, 16*(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: *Studies of welfare populations: Data collection and research issues*, 105-128.

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