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**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Christopher Loss, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0619, [christopher.loss@fda.hhs.gov](mailto:christopher.loss@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of September 30, 2019 (84 FR 51594), FDA published the notice of availability for a draft guidance entitled “Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs” giving interested persons until January 28, 2020, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 2019.

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115).

The guidance represents the current thinking of FDA on eligibility criteria for expanded conditional approval of new animal drugs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910-0032.

##### **III. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 8, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2020-N-1644]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Conference Attendees’ Observations About Prescription Drug Promotion**

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by August 13, 2021.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The title of this information collection is “Medical Conference Attendees’ Observations About Prescription Drug Promotion.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### **Medical Conference Attendees’ Observations About Prescription Drug Promotion**

*OMB Control Number 0910—NEW*

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, advertising features and target populations.

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/officeofmedicalproductsand tobacco/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.

The current study focuses on understanding the landscape of healthcare provider (HCP)-directed promotion of prescription drugs at medical conferences in general and, more specifically, how elements of pharmaceutical booths in medical conference exhibit halls impact HCP attendees' perceptions of the drugs that are promoted at those booths. We will first ask attendees who are prescribers within different disciplines (primary care physicians, specialists, nurse practitioners, and physician assistants) general questions about their attendance at medical conferences, including questions about their motivations for attending, activities they participate in (e.g., symposia, poster sessions, social events, exhibit halls), and their opinions about the prescription drug treatments promoted at medical conferences. These questions will allow us to capture the viewpoint of prescribers who attend medical conferences where prescription treatments are discussed and promoted.

The second part of our study will allow us to get more detailed

information about interactions in medical conference exhibit halls. A 2006 study found that at least 80 percent of physicians attended at least 1 medical conference each year and spent an average of 7 hours on the exhibit hall floor at each event (Ref. 1). The length of time spent at each booth—between 12 and 21 minutes (Ref. 1)—was comparatively longer than detailing visits in HCP offices, which range from 5 to 10 minutes on average (Refs. 2 and 3). Thus, medical conference exhibit booths provide opportunities for pharmaceutical companies to market to large numbers of HCPs and potentially engage in more lengthy interactions.

Promotional booths for prescription drugs and the promotional materials disseminated at those booths fall within the regulatory purview of OPDP. As with other promotional materials for prescription drugs, pharmaceutical companies may voluntarily submit draft versions of their exhibit panels and exhibit materials for FDA review (Ref. 4). This study is designed to provide insights to inform the advisory comments that OPDP provides to pharmaceutical companies that voluntarily seek FDA review. OPDP also monitors prescription drug promotional booths and materials as part of its surveillance program. Recent compliance letters issued by OPDP described booth or panel displays that communicated misleading information regarding drug efficacy and safety, provided insufficient information on drug risks, and omitted "material facts" about the promoted drug (Ref. 5). A primary reason that physicians and other medical professionals report visiting specific exhibitors at conferences is to obtain product information (Ref. 1), and it is important that the information provided by exhibitors to HCPs regarding the risks and efficacy of prescription medications not be false or misleading. Thus, investigating the impact of pharmaceutical booth promotions among medical conference attendees has valuable practical implications for the public health.

As part of our specific exhibit booth research, we will simulate interactions that HCPs may have at medical conference booths promoting prescription drugs, so that FDA can examine the effects of the booth representative's background (scientist/medical professional versus business professional) and disclosure of data limitations (present versus absent). In a recent survey, HCP conference attendees reported that interacting with company representatives was the most important element of their booth visits, followed

by the availability and quality of clinical information (Ref. 4). Thus, the perceived credibility of the booth representative and the availability of information on data limitations could ultimately inform HCPs' perceptions of the risks and benefits of drugs presented at exhibit booths and their decisions to prescribe drugs to patients.

Indeed, literature suggests that credibility and disclosures are relevant elements to study in the context of prescription drug conference booths. Credibility is linked to extrinsic (physical attractiveness, power) and intrinsic (delivery factors, linguistic cues) factors. For example, one extrinsic feature of source credibility is similarity between the source and recipient. Research on the effects of source similarity has been mixed, but a classic field experiment by Brock in 1965 found that customers buying paint were more likely to follow recommendations of a salesperson they perceived as having painting experiences similar to their own (Ref. 6). More recent studies have examined the effects of endorsers with professional expertise versus those with product experience on attitudes toward the brand and promotion (Refs. 7 and 8). These past studies are relevant to our manipulations of booth representative background in this study given that representatives with a medical/science background may reflect professional expertise, whereas representatives with a business background may reflect product experience.

There is little empirical evidence on the impact of disclosing data limitations during promotional detailing or other sales promotion. On one hand, providing important information (e.g., key limitations) about the data/drug should help increase comprehension and decrease inaccurate or unjustified interpretations of the data. On the other hand, seeing the disclosure of data limitations—essentially tempering the study findings and providing a sort of two-sided information that is not necessarily in favor of the drug's effects—may improve the material's credibility and appeal by signifying more transparency on the sponsor's part (Ref. 9), and therefore lead to greater interest in the drug (regardless of accurate comprehension). Conversely, not seeing any qualifying or clarifying information could raise red flags among providers, resulting in the lowest levels of perceived credibility. Whether the booth representative has a medical/science background or business background may shape perceptions of credibility even further, thereby influencing HCPs' perceptions of the drug. Thus, while disclosure of data

limitations and credibility of the booth representative may have independent effects on HCPs’ comprehension and perceptions, these variables could also interact in their effects.

I. Research Questions

With this background in mind, we plan to address the issue of how firms communicate about prescription drugs from the perspective of medical conference/exhibit hall attendees. Specifically, we will ask for attendees’ general observations of:

- a. Disclosures or disclaimers accompanying exhibit hall presentations and/or symposia (about data limitations, contrary data, FDA approval status, financial/affiliation sponsorship, etc.);
- b. Publications or references accompanying the presentation of

information (PI for approved indications, contrary data references, etc.);

- c. What type of studies are being reported (real world evidence, pharmacokinetic/pharmacodynamic studies, meta-analyses, etc.).
- d. Who makes the presentations (field of study, training); and
- e. Where the presentations are made (poster session, scientific floor, exhibit hall); and

We will also address exhibit hall pharmaceutical booth interactions specifically:

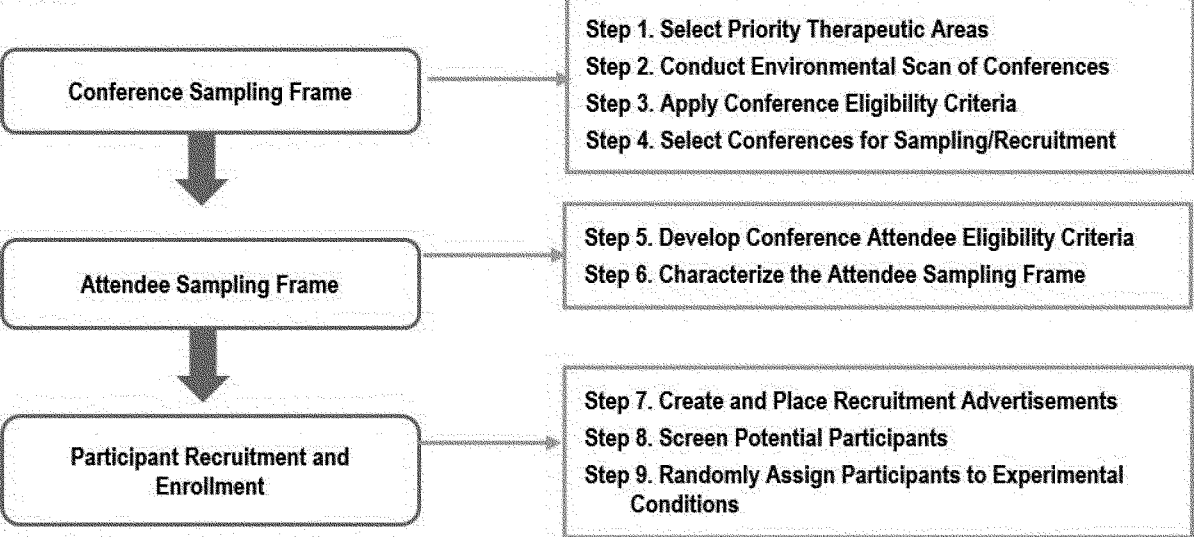
- a. How does the presence or absence of information about the limitations of data influence perceptions of the promoted product?
- b. How does the background of the booth representative influence perceptions of the promoted product?

c. Do these two variables interact?

II. Method

To complete this research, we will recruit attendees of large medical conferences in the United States over the course of 1 year. These conferences will represent a variety of specialties to reflect medical areas that have prescription treatments that may be promoted to HCPs. Specifically, we will enroll HCPs who attended one of 12 selected medical conferences into an online survey within 7 days of conference attendance. Exhibit 1 summarizes our approach to: (1) Determining the conference sampling frame; (2) determining the attendee sampling frame; and (3) recruiting and enrolling the target sample in the online survey.

Exhibit 1. Sampling Frame and Participant Recruitment Process



In the first step, we will select conferences that focused on therapeutic areas that have the following attributes:

- High number of currently promoted branded medications;

- high volume of prescriptions written;
- large patient population; and
- high amount of new drug development and promotional spending.

Exhibit 2 shows the final criterion for conference inclusion. Conferences that meet these criteria will be selected based on an environmental scan.

EXHIBIT 2—CONFERENCE ELIGIBILITY CRITERIA

Criterion	Parameters
Therapeutic area .....	Associated with one of the prioritized therapeutic areas.
Conference attendance .....	Estimated attendance of 5,000 or more individuals.
Target audience .....	Focused on prescribers and clinicians (e.g., not insurers).
Event date .....	Scheduled during August 2021–August 2022.
Event location .....	Domestic (within United States).

Following conference selection, medical conference attendees at each conference will be randomly selected,

invited to participate, and screened to ensure they are HCPs with prescribing authority who responded to the survey

invitation within 7 days of attending the target conference. HCPs will be limited to physicians, nurse practitioners, and

physician assistants who spend 20 percent or more time in direct patient care, are able to read and speak English, are not currently employed by the Federal government or a pharmaceutical company (not including occasional consulting), and have not participated in another wave of the project.

The online survey will be broken into two main parts: (1) A cross-sectional

survey designed to capture HCP observations from the medical conference and (2) an experimental study designed to assess how data disclosures and exhibit booth representative background influence HCP perceptions of promoted prescription drugs. The cross-sectional part of the survey will contain a series of close- and open-ended questions. The

experimental study part of the survey will ask participants to view a brief video simulating a conference exhibit hall interaction between an HCP attendee and a booth employee and then answer questions about a fictitious prescription drug featured in the video. Exhibit 3 shows our proposed study design and sample size across 12 conferences.

### EXHIBIT 3—STUDY DESIGN AND TARGET SAMPLE SIZES

Disclosure	Booth employee background		Total
	Business	Medical	
Present .....	n=92	n=92	184
Absent .....	n=92	n=92	184
Total .....	184	184	368

In the **Federal Register** of September 18, 2020 (85 FR 58366), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six submissions that were PRA-related. One submission (<https://www.regulations.gov/document/FDA-2020-N-1644-0005>) was outside the scope of the research and is not addressed further. Within the remaining five 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 = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

(Comment 1) Five comments expressed support for conducting this research.

(Response 1) Thank you.

(Comment 2) Three comments noted that changes to the research will be necessary due to changes in medical conferences as a result of the emergence of the COVID-19 pandemic, such as the move to all-virtual conferences.

(Response 2) We agree with these comments. Section 1 of the questionnaire (Video observation) is unaffected by whether participants have recently attended a conference, so we have not changed this section. Section 3 (Typical Conference Behaviors) is also unaffected by recent conference attendance. However, we added an instruction that participants should answer about their behavior prior to

COVID-19 restrictions. Most of the questions in Section 4 (Participant Characteristics) are unaffected by recent conference attendance. However, we updated questions about patient load and prescription volume to include both in-person and telemedicine visits. Section 2 (Recent Conference Behavior) does assume participants have recently attended a conference. We have replaced some of the questions that are less likely to be relevant (e.g., receipt of materials) with open-ended questions asking about the exhibit hall experience and interactions with pharmaceutical company representatives during a virtual conference.

(Comment 3) One comment suggested adding a control arm comprised of physicians who have not attended a medical conference during the same period and asking them about their perceptions of the same products in order to determine to what extent medical conferences are influencing physician perceptions of products.

(Response 3) This comment is outside the scope of the current research. Researchers may want to explore additional questions in this area for future studies.

(Comment 4) One comment suggested that because the video is not interactive, it may not capture all possible questions that a conference attendee may have.

(Response 4) The comment is correct that the video consists of a prerecorded interaction between a conference attendee and a booth representative. We recognize that this does not cover all possible communications at a conference. We appreciate the suggestion about the use of interactive simulation, but it would disrupt the experimental design by creating unnecessary variation in the stimuli.

The limitations of the current method will be transparent in the dissemination of our findings.

(Comment 5) Two comments mentioned that, if we are concerned about subject bias, differences in age, gender, and race/ethnicity between the pharmaceutical representative and the prescriber in the video should be controlled for.

(Response 5) The videos are identical in every way except for the job description of the booth representative and whether a disclosure is present to the data described. This means that not only are the actors the same, but almost all footage in the video is the same. Additionally, participants will be randomly assigned to experimental conditions. Thus, age, gender, and race/ethnicity will not factor into our assessment of whether a booth representative's job description or the presence of a disclosure influences participant responses.

(Comment 6) Two comments cautioned FDA against drawing conclusions about all promotional details based on survey responses for one video. These comments suggested that FDA use multiple videos, rather than just one, to depict different approaches to promotion and re-design the study to conduct a post-conference message recall study to allow FDA to better meet the objectives of the study.

(Response 6) The current study is largely a survey about medical conference attendance in general and more specifically at a recent conference. Our objective, as outlined in the text of the 60-day notice, is to use those questions to assess self-reported opinions about participants' experiences at a variety of conferences. Within the study is an embedded experimental

manipulation to address two very specific questions: whether the credentials of a booth representative make a difference in terms of the observers' perceptions of the promoted product, and whether a disclosure of information is processed by observers. In this part, participants will see one of four videos that are identical except for the credentials of the booth representative and the presence or absence of a disclosure. FDA will not use the video to generalize beyond these questions. Because participants will be randomly assigned to video conditions, we will be able to make causal claims—but only about the specific items (credentials and disclosure) we vary.

(Comment 7) One comment requested that we provide the public with an opportunity to preview and comment on the videos to be used in future research proposals.

(Response 7) 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 our research. In our research proposals, we describe the purpose of the study, the design, the population of interest, and the estimated burden.

(Comment 8) One comment mentioned that although limiting participants to those who respond to the survey within 7 days creates a selection bias, it is a feasible method. The comment suggested that we also screen for amount of time participants spent on the exhibit hall floor, rather than relying on average numbers of hours spent at exhibition halls.

(Response 8) We are limiting the sample to participants who attended a medical conference within 7 days to minimize retrospective errors that may occur as time passes. We appreciate the suggestion that we add a question about how much time is spent at the exhibition hall, and we have incorporated it into the questionnaire.

(Comment 9) One comment suggested that, given the international scope of many conferences, the screener should ensure that HCPs practice in the United States.

(Response 9) Our sample will be limited to U.S.-based HCPs with prescribing authority.

(Comment 10) One comment suggested that specific knowledge of OPDP regulatory requirements may be limited and, if known, it may increase credibility of booth representatives. The commenter suggests adding questions about regulatory knowledge.

(Response 10) Past OPDP studies have examined HCPs' familiarity with

promotional regulation (*e.g.*, OMB control number 0910–0869). We have consistently found that only a small percentage of providers know whether FDA regulates prescription drug promotion, and we believe even fewer would have specific knowledge of OPDP's particular regulatory authorities. Given that we have investigated this topic in the past and we find most providers to be unfamiliar with regulatory roles, we will leave such questions out of the study to reduce burden.

(Comment 11) One comment suggested the inclusion of additional questions about the perceived credibility of the booth representative, the likelihood of recommending the prescription drug, or the desire to conduct further inquiries for the product.

(Response 11) We have included questions about booth representative credibility and intention to prescribe.

(Comment 12) One comment suggested that it would be useful to add questions about the participants' backgrounds, such as familiarity with prescription drug promotion, age, specialty, personal medical/professional school debt, exposure to pharmaceutical marketing practices, and whether they practice in an urban or rural area.

(Response 12) We have questions about age, medical specialty, and exposure to pharmaceutical marketing practices. We will include a question about the rural versus urban location of their practices. We decline to ask about personal medical school debt because it is not clear how this will influence pharmaceutical promotions in a conference exhibit hall.

(Comment 13) One comment suggested adding questions about aspects of promotional exhibit halls other than the booth representative.

(Response 13) This comment is outside the scope of the current research. Researchers may want to explore additional questions in this area for future studies.

(Comment 14) One comment noted that it would be helpful to track whether advertisements outside of the exhibit hall encouraged providers to visit certain booths within the exhibit halls.

(Response 14) This comment is outside the scope of the current research. Researchers may want to explore additional questions in this area for future studies.

(Comment 15) One comment recommended keeping the focus of Section 2 (recent conference behaviors) on general conference behaviors and moving all product perception questions to Section 1.

(Response 15) Section 1 involves the specific manipulation of booth representative credentials and the presence/absence of a disclosure. Section 2 involves asking participants about a recent conference experience. The advantage of this approach is that we can get more specific information not influenced by retrospective guessing. The opportunity to ask specific questions is one of the strengths of the current study.

(Comment 16) One comment mentioned that the questions make use of the term “booth,” while the **Federal Register** notice speaks to “promotional booth” and suggested that the survey questions use the term “promotional booth” for clarity and consistency.

(Response 16) We have made this change.

(Comment 17) One comment mentioned that the questions use the term “industry representative” or “drug representative” and suggested the survey employ the term “industry representative” exclusively to ensure clarity and consistency.

(Response 17) We have revised the questionnaire to consistently use the term “industry representative.”

(Comment 18) One comment suggested we change the wording of questions using the term “exhibit hall” to refer instead to “promotional booths located in the exhibit hall,” which is more focused.

(Response 18) We have made this change.

(Comment 19) One comment suggested that for Questions 6–11, the survey taker's responses can be influenced by other factors not necessarily related to the content provided in the video, thus leading to inconclusive results about the video presented.

(Response 19) Questions 6–11 refer to the experimental manipulation in the video (see Response 6). Because we will have random assignment to condition and the only differences in the videos will be the credentials of the booth representative and the presence or absence of a disclosure, we will be able to make causal claims if we see differences in responses across conditions.

(Comment 20) One comment suggested that to eliminate the risk of bias in the survey questions related to safety and efficacy, study participants should be asked *whether* they think that the promoted drug is safer and *whether* they think that the promoted drug is more efficacious as compared to another drug.

(Response 20) This comment appears to refer to Questions 8 and 9. These are

validated questions that have been used in previous studies (Ref. 10).

Development and validation of prescription drug risk, efficacy, and benefit perception measures in the context of direct-to-consumer prescription drug advertising. *Research in Social and Administrative Pharmacy*. Moreover, the scale ranges from “Strongly Agree” to “Strongly Disagree,” so no bias is implied.

(Comment 21) One comment suggested that Questions 13 and 14 are specific to one risk and that this risk may not pertain to all situations, such as treatments for serious and life-threatening conditions. The comment expressed confusion regarding how conclusions from these questions can be applied to all drugs promoted at a convention.

(Response 21) We specifically ask questions about this risk because this is the risk that relates to the disclosure manipulation. These questions will be used to determine if the presence of a disclosure influences participants’

responses to the relevant information in the ad.

(Comment 22) One comment suggested that Questions 22 and 23 should be reworded to define what part of the conference (poster session, exhibit hall, oral sessions, etc.) the words “conference sessions” are referring to.

(Response 22) We have now specified “oral and poster sessions” in these questions.

(Comment 23) One comment suggested that followup questions should be added for participants that answer “Yes” to Question 24 as follows:

What was the background of the person who made this presentation?

- *Answer Options:* Scientific background, Business background.

What part of the conference was this presentation presented at?

- *Answer Options:* Symposia/Oral sessions, Workshops, Poster sessions, Exhibit hall.

(Response 23) We considered adding these questions to the questionnaire.

However, after adapting the survey for a current and post-COVID–19 world, these questions were ultimately not included so that the information collection could stay within the proposed burden estimate.

(Comment 24) One comment suggested that Question 30 should be reworded so that it is specific to the particular types of materials checked in Question 29.

(Response 24) We have removed Question 30 from the questionnaire due to time constraints.

(Comment 25) One comment recommended the addition of a choice that reads, “met with the sales representative virtually,” for Question 51, as this has been occurring more frequently during the COVID–19 pandemic.

(Response 25) This response option was added.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener .....	933	1	933	.08 (5 minutes) .....	74.64
Pretest .....	25	1	25	.33 (20 minutes) ....	8.25
Main test .....	368	1	368	.33 (20 minutes) ....	121.44
Total .....	.....	.....	.....	.....	204.33

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

### III. References

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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Dated: July 7, 2021.

**Lauren K. Roth,**  
Acting Principal Associate Commissioner for Policy.

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