

United States Food and Drug Administration

Medical Conference Attendees' Observations about 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 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.

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% 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, 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, 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.

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);
- e. Where the presentations are made (poster session, scientific floor, exhibit hall).

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?

2. Purpose and Use of the Information Collection

The purpose of this research is to provide information to inform FDA generally about the landscape of medical conferences and specifically about promotional prescription drug booths, where considerable promotion occurs. This knowledge will assist FDA's understanding of a commonly used venue for prescription drug promotion.

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 attendee's perceptions of prescription drug promotion directly after conference attendance.

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 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 (*regulations.gov* tracking number *khm-1xs7-vfn8*) 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 seven 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 seven 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 U.S.

(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 No. 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 (see Kelly, B.J., Rupert, D.J., Aikin, K.J., Sullivan, H.W., Johnson, M., Bann, ... & Peinado, S. (2021). 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*, 17(5), 942-955). 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 follow-up 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.

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:

Colette DeJong, MD
Resident Physician
University of California—San Francisco
San Francisco, CA

David Stewart, PhD
Professor of Marketing
Loyola Marymount University
Los Angeles, CA

9. Explanation of Any Payment or Gift to Respondents

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. 10) 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. 11-15) 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 kept secure to the extent permitted by law 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. Medscape/WebMD already has PII such as names and contact information from people in its research database from which participants will be recruited. Medscape/WebMD 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 Medscape/WebMD 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 Medscape/WebMD. 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. Medscape/WebMD 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 Burden¹

	No. of respondents	No. of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener	933	1	933	.08 (5 min)	74.64
Pretest	25	1	25	.33 (20 min)	8.25
Main test	368	1	368	.33 (20 min)	121.44
Total					204.33

¹There are no capital costs or operating 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 \$499,832 (\$124,958 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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