necessary information, prepare, and submit to FDA. We estimate that sponsors with inactive applications will spend 2 hours preparing their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping required by section 512(l)(3) of the FD&C Act	23	1	23	2	46

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

Animal drug manufacturers are already required to maintain distribution records for their animal drug products to comply with FDA's current good manufacturing regulations for periodic drug reports under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)), approved under OMB control number 0910–0284. Section 512(l)(3) of the FD&C Act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. In addition, under 21 CFR 211.196 (approved under OMB control number 0910–0139), manufacturers currently are required to maintain distribution records that include dosage form, and date drug is distributed. Based on these requirements, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of usual and customary business practices. However, FDA estimates an additional recordkeeping burden of 46 hours for further compliance with section 512(l)(3), as detailed in table 2.

After a review of the information collection since our last request for OMB approval, we have adjusted our estimates based on our experience with the antimicrobial animal drug distribution reports program. Our estimated burden for the information collection reflects a decrease of 54 burden hours and a corresponding decrease of 27 total annual responses. We attribute this to respondents who submitted by paper in previous years and are now reporting electronically.

Dated: October 18, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24721 Filed 10–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3768]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adherence Potential and Patient Preference in Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 November 25, 2024.

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 ''Adherence Potential and Patient Preference in Prescription Drug Promotion.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@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.

Adherence Potential and Patient Preference in 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 mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotion 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 the characteristics of the disease and product 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. 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 the first topic area, advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are 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 home page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research*. The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

The study described in this notice builds on OPDP's portfolio of research on market claims and disclosures to explore the influence of statements around patient adherence and preference in prescription drug promotion. Previous FDA-funded research has shown that market claims that advertise drug characteristics unrelated to medicinal properties, such as ''#1 Prescribed,'' influence consumer and provider perceptions about a drug's efficacy (Ref. 1). In the same study, results of a tradeoff analysis suggested that patients prefer a drug over a competitor when this type of claim is present, and a drug without this claim required at least 1.23 percent greater efficacy to be chosen over a drug with this claim (Ref. 2). Treatment preferences may also be influenced by other drug characteristics, including its impact on quality of life, complexity of dosage regimens, administration mode, and cost to family and self (Refs. 3, 6, and 8).

It is not known how claims that appeal to the possibility for greater adherence or to social norms around what other patients or healthcare providers prefer influence perceptions of a drug. A related question is whether including a disclosure stating the uncertainty around such claims (*e.g.,* there is no conclusive research on whether DRUG A results in better adherence) can mitigate any misleading perceptions or influence preferences. Some evidence suggests that disclosures in prescription drug promotion are typically noticed and may help consumers and healthcare providers understand information (Refs. 2 and 4), but this topic has not been investigated in the context of adherence claims.

The present research is designed to complement previous research by experimentally examining the role of adherence and patient preference claims in prescription drug promotion.

Research questions:

1. Does the presence or absence of an implied adherence claim affect consumers' and primary care physicians' (PCPs') behavioral intentions or risk, benefit, and adherence perceptions?

2. Does the presence or absence of an adherence-related patient preference claim affect consumers' and PCPs' behavioral intentions or risk, benefit, and adherence perceptions?

3. Does the presence of both types of claims (adherence and preference) have a cumulative impact on consumers' and PCPs' behavioral intentions or risk, benefit, and adherence perceptions?

4. Does a disclosure of information to the effect that there is no conclusive research on whether the drug results in better adherence mitigate consumers' and PCPs' behavioral intentions or risk, benefit, and adherence perceptions?

To complete this research, we propose the following design for a total of 8 study conditions: 2 (patient preference claim) × 2 (adherence claim) × 2 (disclosure).

TABLE 1—STUDY DESIGN (IMPLIED ADHERENCE CLAIM) × 2 (PATIENT PREFERENCE CLAIM) × 2 (DISCLOSURE)

	With disclosure [1]		Without disclosure	
	Patient preference claim		Patient preference claim	
	Yes	No	Yes	No
Implied Adherence Claim	Yes.			
	No.			

[1] E.g., ''There is no evidence to suggest better adherence to Drug X compared with Drug Y.''

We will recruit the following numbers of participants for the pretest and main study surveys:

- 320 individuals for the pretest (n = 160 consumers and n = 160 PCPs); and
- 720 individuals for the main study (n = 360 consumers and n = 360 PCPs)

Each participant will see one of eight versions of a static web page for a fictitious prescription type 2 diabetes treatment, as reflected in table 1. They will answer a survey designed to take no more than 15 minutes to complete regarding their perception of the product's benefits, risks, and effect on adherence. Consumers and PCPs will receive slightly different versions of the web page and survey, and their data will be analyzed separately.

In the **Federal Register** of October 12, 2023 (88 FR 70669), FDA published a 60-day notice entitled ''Agency Information Collection Activities; Proposed Collection; Comment Request; Adherence Potential and Patient Preference in Prescription Drug Promotion,'' requesting public comment on the proposed collection of information. FDA received two submissions, one of which included multiple comments. Responses to all comments follow. For brevity, some public comments are paraphrased and, therefore, may not state the exact language used by the commenter. All comments were considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: healthcare professional (HCP); Food and Drug Administration (FDA or Agency); and FDA's Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research (OPDP).

(Comment 1) One comment supported the OPDP research program and the current proposed study, with a question as to whether research on disclosures has been previously conducted.

(Response 1) We appreciate this comment for its support of this research and our research program. In response to the query in this comment, OPDP has conducted studies on the topic of disclosures in prescription drug promotion (found at the website listed previously in this document), but none that have addressed disclosures specific to adherence or preference claims.

(Comment 2) One comment inquired whether the Agency intends to publish

the results of this study. If so, the comment inquired whether publication will be in the form of a publicly available report or a peer-reviewed publication.

(Response 2) 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 an internet posting.

(Comment 3) One comment inquired whether the Agency intends to seek an approval or exemption from an Institutional Review Board (IRB) or ethics committee.

(Response 3) The research will be reviewed for exemption by the IRB of record, which will be the FDA contractor's (Westat's) IRB.

(Comment 4) One comment inquired how the Agency will ensure that the samples are representative of the relevant populations, and it asked whether there will be stratification of the sample by specific demographic or clinical characteristics.

(Response 4) The project will recruit individuals from two populations: adult consumers diagnosed with type 2 diabetes and PCPs. For each study segment, internet vendor AllGlobal will recruit study participants using their proprietary panels. Several methodologies are used by AllGlobal to recruit panelists, including opt-in email, co-registration, e-newsletter campaigns, and internal and external affiliate networks. To recruit consumers, AllGlobal will use their LifePoints panel of more than 5.5 million consumers. To recruit PCPs, AllGlobal will use its Global Professional Panel, which includes access to over 2 million physicians, nurses, and other interested healthcare parties across a wide range of therapy areas. AllGlobal uses various metrics to track panel member activity and engagement, which enhances the efficiency of recruitment and quality of survey data from their panelists.

Participants will be drawn from convenience samples, rather than probability-based samples. We will aim for a diverse mix of participants in terms of race/ethnicity, gender, age, and other characteristics, but we will not specifically stratify the data before collecting it. Moreover, no weighting of the data will be required because the objective of the studies is to estimate the causal effects of experimental manipulations rather than to estimate descriptive statistics for these populations.

(Comment 5) One comment notes that Questions 7 and 8 of the questionnaire ask respondents whether HCPs and patients prefer FENTIVA. Considering these questions, the comment suggests that the web page include such statements with appropriate context. For example, the web page might post language such as ''more patients prefer FENTIVA versus [Insert product].'' In addition, the comment suggests it would be appropriate for the web page to also include a statement referencing the study from which this information was derived. For example, the comment notes that the preference information presented on the website for RITUXAN HYCELA (rituximab and hyaluronidase human) injection includes the following statement: ''In a study of previously untreated DLBCL and follicular lymphoma patients, 77 percent of patients preferred subcutaneous administration of RITUXAN HYCELA over intravenous rituximab as it required less time in clinic.''

The comment states that without seeing the stimulus to which participants will be asked to respond, there is uncertainty about the purpose of these questions. If these questions are meant to assess participants' understanding of the information on the web page, then the comment suggests that the question ask the participant to choose the correct statement from a set of statements in which all but one is incorrect. The comment further suggests that if these questions are meant to assess the impression that a participant gets from the information presented on the web page, then responses to these questions likely cannot be interpreted directly.

Lastly, the comment recommends that the Agency clarify the purpose of Questions 7 and 8 and ensure that the conclusions that will be drawn by the responses to these questions can be supported based on the questions themselves and the response options provided to participants.

(Response 5) We appreciate these comments and offer a few points of clarification. Questions 3–11 are intended to assess participants' recall of information provided in the stimuli (website). For example, the statement ''Doctors prefer FENTIVA over other medications to control blood sugar.'' Question 7 was not mentioned on the website and is asked as a foil. These questions will allow us to determine whether participants' read the stimuli carefully and thus serve as an attention check.

Participants' gist comprehension of the information will be assessed through a different series of questions using a True/False format.

We also address the suggestion to include a statement referencing the study from which the preference information is derived (as is done with the RITUXAN HYCELA website). A key aim of our study is to test the effect of a disclosure statement on perceptions when no such evidence on adherence exists (*e.g.,* ''There is no clinical evidence suggesting better treatment adherence with once-monthly FENTIVA injection compared to daily tablets''). For this reason, we chose not to provide clinical information on preference or adherence in our study stimuli, although we acknowledge that some promotions indeed include this information when available.

(Comment 6) One comment notes that Question 7 reads, ''Doctors prefer FENTIVA over other medications to control blood sugar.'' The comment suggests clarifying the wording. Specifically, the comment suggests that doctors do not have preferences for medications. Instead, doctors ''would be more likely to choose to prescribe one option over another.'' In addition, doctors prescribe medications to patients with a condition. Therefore, the comment suggests revising ''medications to control blood sugar'' to read, ''for patients who need to control their blood sugar.''

(Response 6) We appreciate the second point and have changed Question 7 to read: ''Doctors prefer FENTIVA over other medications for patients who need to control their blood sugar.'' We also refer to our previous explanation (Response 5) about the intent of this item, which is to test recall of information on the website, where the statement about doctors' preferences for FENTIVA was not mentioned on the website and thus included in this survey as a foil.

(Comment 7) One comment suggests that Question 9 is difficult to evaluate without seeing the materials that will be presented to participants. Specifically, the comment notes that if the web page does not say explicitly that the patient doesn't have to think about taking medication every day, but instead says that FENTIVA is taken once a month rather than every day, whether a patient ''no longer has to think about taking medication'' could be considered leading, and interpreting the results of this question could be problematic. Therefore, the comment recommends that the Agency clarify the purpose of Question 9 and ensure that there is no ambiguity in how the responses to the question will be interpreted.

(Response 7) As explained above, items 3–11 assess recall of information that may or may not have been presented on the website. The statement ''With once-monthly FENTIVA injections, I no longer have to think

about taking medication every day'' is presented on the website. The intent of the question is to assess whether participants read and paid attention to key statements.

(Comment 8) One comment opines that Questions 10 and 11 are difficult to interpret without seeing the information that will be provided to participants. However, the comment continues, the pair of questions taken together seem to indicate that one statement is correct while the other is not. If the purpose of the questions is to test recall, then it would be more appropriate to include both statements in a single question and ask respondents which is correct. If the purpose of the questions is to test the impression that participants get from the information presented in the web page, then there may be no objectively correct answer to the question that does not mirror exactly what is stated in the web page. Therefore, the comment recommends that the Agency clarify the purpose of Questions 10 and 11 and ensure that there is no ambiguity in how the answers to these questions will be interpreted.

(Response 8) We refer to our previous explanation (Response 5) about the intent of these items. To clarify further, consumers and PCPs will receive slightly different versions of the same disclosure statement on the website. Thus, only the consumer group will be asked Question 10 and only the PCP group will be asked Question 11.

(Comment 9) One comment notes that Question 14 asks whether it is true or false that ''FENTIVA is given as a shot with a needle.'' The comment states that this statement could be interpreted that FENTIVA is administered using a syringe with an exposed needle. If the web page states that the medication is given using an autoinjector, pen, or another device, it may be technically true that the medication is given as a shot with a needle. But it is also plausible that a reasonable person would say that this is untrue because they interpret ''shot with a needle'' to describe only a syringe with an exposed needle. The comment recommends that the Agency review this question to ensure that there is no ambiguity in participant's interpretation of the statement or in the Agency's interpretation of the results.

(Response 9) We agree with the concern raised in this comment and have since revised this item to read: ''FENTIVA is given as an injection under the skin'' (True/False) as a measure of comprehension.

(Comment 10) One comment notes that Question 15 asks participants to indicate ''what you know.'' The comment states that because FENTIVA is a hypothetical product and participants are responding to a specific set of information, asking participants ''what you know'' may be an imprecise question. Therefore, the comment recommends that the Agency consider revising the question to read: ''Please indicate which of the following statements best describes what you understand about FENTIVA based on the information provided in the web page.''

(Response 10) We have revised the question to read: ''Please indicate which of the phrases below best completes this statement about FENTIVA, based on what you read on the website.''

(Comment 11) One comment notes that Question 16 presents two statements which are suggested to come from the stimulus material. The comment notes that both statements could be considered incomplete because they mention a specific injection product (''FENTIVA'') contrasted with an unnamed oral medication. The implication is that the oral tablets are an alternative to FENTIVA for achieving the same clinical outcome. However, the comment notes that this conclusion is not included in the stimulus material and recommends that the use of the oral tablet as an alternative for the same condition be stated explicitly.

(Response 11) The language presented in Question 16 refers to the disclosure statements as they appear on the stimuli: ''There is no evidence that patients who choose once-monthly FENTIVA injections are more likely to follow their prescribed treatment plan compared to those who choose daily tablets'' (consumer version) or ''There is no clinical evidence suggesting better treatment adherence with once-monthly FENTIVA injection compared to daily tablets'' (HCP version). We intentionally do not state that FENTIVA injection achieves the same clinical benefit as oral daily tablets, as we ask later about participants' perceptions of comparative efficacy, based on the information provided in the stimuli.

(Comment 12) One comment notes that in Questions 17–19, the questions related to importance and usefulness likely require context—important in what way and/or useful in what way? The comment suggests that without clarification, the interpretation of the responses to these questions would be subject to ambiguity and recommends changing ''useful'' to ''useful in . . .'' and ''important'' to ''important for . . . .''

(Response 12) These questions are derived from theory and validated scales on ''perceived message effectiveness.'' This construct is often measured as a set of close-ended judgments such as ''useful/not useful'' and estimate the degree to which recipients of that message will favorably (or unfavorably) evaluate a message. Identifying why or how the message is considered useful/relevant could be assessed with further questions but is not a focus of this research. Rather, we are interested in participants' more general perceptions of message effectiveness and will compare responses across study arms (Ref. 5).

(Comment 13) One comment suggests that Questions 20–24 include language that could be considered leading. Therefore, the comment recommends changing the questions to capture whether the participant assessed the statement to be true or false and changing the response options to ''true,'' ''false,'' or ''I don't know.''

(Response 13) We have chosen to use a Likert scale (1 = would not help at all/ 5 = would help very much) rather than a true/false scale for these items as the intent is to assess the extent to which participants perceive the drug to be beneficial/efficacious. We also note that these items were adapted from validated scales on perceived benefit and risk (Ref. 7).

(Comment 14) One comment suggests that Question 27 includes language that could be considered leading and recommends changing the question to capture whether the participant assessed the statement to be true or false and changing the response options to ''true,'' ''false,'' or ''I don't know.''

(Response 14) See Response 13 and the referenced citation above. We have chosen to measure benefit and risk perception using Likert scales and note that these measures come from validated scales.

(Comment 15) One comment suggests clarifying whether in Questions 29 and 30, ''other daily prescription drugs that treat type 2 diabetes,'' includes insulin or other injectable options or is limited to oral options only.

(Response 15) These questions are intended to assess perceptions of the convenience of FENTIVA compared to any other type 2 diabetes drug taken daily.

(Comment 16) One comment suggests that the language in Question 31 could be considered leading. The question asks about likely adherence to a medication over a long period of time during which a patient may experience side effects or lack of efficacy. Therefore, a likelihood to get injections every month assumes that a patient does not have a reason for discontinuing. In addition, the comment notes that it is

not clear whether the injections are prescribed instead of an alternative or in addition to an alternative. The comment recommends that the Agency make the assumptions behind the question explicit to the participant.

(Response 16) The reasons mentioned in this comment are the reasons OPDP found it valuable to conduct this study. Those are possible reasons that it could be misleading to suggest that receiving a monthly injection is easier or results in greater adherence than a daily pill. FDA has designed this study to keep our questions as simple as possible, consistent with good practices, to reduce burden on participants. We specifically keep extraneous factors out of the questions to glean what we intend to study. Here, we are interested to know if behavioral intentions around adherence vary by experimental arm. Would information on the website around patient preference or disclosure about the lack of evidence on adherence influence behavioral intentions?

(Comment 17) One comment suggests that Questions 33–35 likely overstate the type of evidence that would be used for this purpose and recommends rephrasing the question in each case to read, ''Knowing that more patients preferred FENTIVA monthly injections than other daily prescription drugs . . . .''

(Response 17) We have removed these items from the survey.

The total annual estimated burden imposed by this collection of information is 1,293 hours (table 2). 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 participant samples in the study.

Note that this burden chart differs in certain respects from the chart published in the 60-day **Federal Register** notice. The previous burden chart assumed a 70 percent estimated eligibility for the consumer group; the current chart has adjusted this estimate to 5 percent. The previous chart incorrectly assumed that the vendor already had eligibility information for this panel, and we could specifically target those with this medical condition. Thus, the larger burden estimate is the more accurate, as we will need to screen a larger number of people. We also adjusted the HCP estimate to reflect what we believe is a more accurate projected eligibility of 50 percent.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PCPs:					
Pretest screener completes (assumes 50 percent eligibility rate).	352	1	352	0.08 (5 min.)	28
Pretest number of completes	176	1	176	0.25 (15 min.)	44
Main study screener completes (assumes 50 percent eligibility rate).	792	1	792	0.08 (5 min.)	63
Main study number of completes	396	1	396	0.25 (15 min.)	99
Consumers:					
Pretest screener completes (assumes 5 percent eligibility rate).	3,520	1	3,520	0.08 (5 min.)	282
Pretest number of completes	176	1	176	0.25 (15 min.)	44
Main study screener completes (assumes 5 percent eligibility rate).	7,920	1	7,920	0.08 (5 min.)	634
Main study number of completes	396	1	396	0.25 (15 min.)	99
Total					1,293

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

References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. 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.

1. Aikin, K.J., K.R. Betts, A. Keisler, and K.S. Ziemer, ''Market Claims and Efficacy Information in Direct-to-Consumer Prescription Drug Print Advertisements,'' *Psychology & Marketing,* 36(8), 747–757 (2019).
2. Aikin, K.J., K.R. Betts, K.S. Ziemer, and A. Keisler, ''Consumer Tradeoff of Advertising Claim Versus Efficacy Information in Direct-to-Consumer Prescription Drug Ads,'' *Research in Social and Administrative Pharmacy,* 15(12), 1484–1488 (2019).
3. Arroyo, R., A.P. Sempere, E. Ruiz-Beato, D. Prefasi, et al., ''Conjoint Analysis To Understand Preferences of Patients With Multiple Sclerosis for Disease-Modifying Therapy Attributes in Spain: A Cross-Sectional Observational Study,'' *BMJ Open,* 7(3), e014433 (2017).
4. Betts, K.R., V. Boudewyns, K.J. Aikin, C. Squire, et al., ''Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements,'' *Research in Social and Administrative Pharmacy,* 14(10), 951–963 (2018).
5. Dillard, J.P., K.M. Weber, and R.G. Vail, ''The Relationship Between the Perceived and Actual Effectiveness of Persuasive Messages: A Meta-Analysis With Implications for Formative Campaign Research,'' *Journal of Communication,* 57(4), 613–631 (2007).
6. Fraenkel, L., L. Suter, C.E. Cunningham, and G. Hawker, ''Understanding Preferences for Disease-Modifying Drugs in Osteoarthritis,'' *Arthritis Care Research,* 66(8), 1186–1192 (2014).
7. Kelly, B.J., D.J. Rupert, K.J. Aikin, H.W. Sullivan, et al., ''Development and Validation of Prescription Drug Risk, Efficacy, and Benefit Perception Measures in the Context of Direct-to-Consumer Prescription,'' *Research in Social and Administrative Pharmacy,* 17(5), 942–955 (2021).
8. Wouters, H., G.A. Maatman, L. Van Dijk, M.L. Bouvy, et al., ''Trade-Off Preferences Regarding Adjuvant Endocrine Therapy Among Women With Estrogen Receptor-Positive Breast Cancer,'' *Annals of Oncology,* 24(9), 2324–2329 (2013).

Dated: October 18, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24720 Filed 10–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4732]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The Committee will discuss Considerations for Respiratory Syncytial Virus (RSV) Vaccine Safety in Pediatric Populations and will also hear overviews of the Laboratory of Immunoregulation (LI) and Laboratory of Retroviruses (LR) research programs in the Center for Biologics Evaluation and Research. At least one portion of the meeting will be closed to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on December 12, 2024, from 8:30 a.m. to 5:30 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

The online web conference meeting will be available at the following link on the day of the meeting: *https://youtube.com/live/f0bNPpqAy-M*.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–4732. The docket will close on December 11, 2024. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before December 4, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–4732 for ''Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

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.

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