evaluation of diagnostic radiopharmaceuticals in this information collection is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles by enabling manufacturers to tailor information submissions and avoid unnecessary clinical trials.

In table 1, row 2, we estimate the annual reporting burden for preparing the safety and effectiveness sections of a supplement to an approved application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that one submission will be received annually. We estimate the total time needed to prepare complete applications for supplements to new applications for diagnostic radiopharmaceuticals as approximately between 500 and 1,000 hours. We calculated the median of this estimate to arrive at approximately 750 hours. We further estimate that the total time needed to prepare the portions of the application that would be affected by this information collection as 750 hours. As previously stated, this information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 750 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR NDAS AND SUPPLEMENTS TO APPROVED NDAS FOR DIAGNOSTIC RADIOPHARMACEUTICALS [1]

Manufacturers' activity (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
NDAs (§§ 315.4, 315.5, and 315.6)	3	1	3	2,000	6,000
Supplements to Approved NDAs (§§ 315.4, 315.5, and 315.6)	1	1	1	750	750
Total					6,750

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

Since our last OMB approval, our estimated burden for the information collection reflects an overall decrease of 11 responses with a corresponding decrease of 12,000 burden hours. We attribute this adjustment to a decrease in the number of submissions for NDAs for diagnostic radiopharmaceuticals and new indication supplements for diagnostic radiopharmaceuticals we received over the past few years.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22460 Filed 10–11–23; 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; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Adherence Potential and Patient Preference in Prescription Drug Promotion.''

DATES: Either electronic or written comments on the collection of information must be submitted by December 11, 2023.

ADDRESSES: You may submit comments as follows. 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, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2023–N–3768 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Adherence Potential and Patient Preference in Prescription Drug Promotion.'' 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.'' The Agency 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 to 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 this 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.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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,* which includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

This study 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. 3–5).

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 6), 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. We have the following specific questions:

Research questions:

1. Does the presence or absence of an implied-adherence claim affect consumers' behavioral intentions or risk, benefit, and adherence perceptions?

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

To complete this research, we will show participants a website for a fictitious prescription drug product for type 2 diabetes. We propose the design in table 1, which varies based on whether the fictitious prescription drug promotional communication includes a claim about:

- implied adherence;
- patient preference; and
- a disclosure that there is no conclusive research on adherence.

TABLE 1—DESIGN 2 (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 conclusive research to suggest better adherence to Drug X compared with Drug Y."

Recruitment will occur by email through an internet panel, and participant eligibility will be determined with a screener at the beginning of the online survey. For the pretest, we expect to screen 253 consumers and 294 primary care physicians (PCPs) to reach our desired number of completed surveys. We will conduct complete pretest surveys with 160 consumers who self-identify as having been diagnosed with diabetes and 160 PCPs who treat diabetes (both obtained from a web-based research vendor) to ensure that the questionnaire programming works as expected. For the main study, we expect to screen 566 consumers and 660 PCPs to reach our desired number of completed surveys. Thus, for the main study final sample, we will recruit 360 adult voluntary participants aged 18 years or older who self-identify as having been diagnosed with diabetes and 360 voluntary participants who are employed as PCPs who treat diabetes. We will exclude individuals who work in healthcare settings, employees of the Department of Health and Human Services, and individuals who work in the marketing, advertising, or pharmaceutical industries.

The total annual estimated burden imposed by this collection of information is 520 hours (table 2). These estimates account for over-recruitment of 10 percent to account for survey incompletes. 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.

Each participant will see one of eight versions of a consumer web page for a fictitious prescription diabetes treatment, as reflected in table 1. They will answer a questionnaire designed to take no more than 20 minutes regarding benefit and risk perceptions, adherence perceptions, behavioral intentions, adherence claim retention, and patient preference claim retention. The survey is available upon request at *DTCresearch@fda.hhs.gov.*

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Pretest:					
Consumers: pretest screener completes (assumes 70% eligible).	253	1	253	0.08 (5 min.)	20
Consumers: number of completes, pretest	176	1	176	0.33 (20 min.)	58
PCPs: pretest screener completes (assumes 60% eligible).	294	1	294	0.08 (5 min.)	24
PCPs: number of completes, pretest	176	1	176	0.33 (20 min.)	58

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Main Study:					
Consumers: number of main study screener completes (assumes 70% eligible).	566	1	566	0.08 (5 min.)	45
Consumers: number of completes, main study	396	1	396	0.33 (20 min.)	131
PCPs: number of main study screener completes (assumes 60% eligible).	660	1	660	0.08 (5 min.)	53
PCPs: number of completes, main study	396	1	396	0.33 (20 min.)	131
Total (rounded)	.....	.....	.....	.....	520

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

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, 2019a.
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, 2019b.
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. 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.
5. 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.
6. 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.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22586 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations for Voting Members for the Digital Health Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for voting members, excluding consumer and industry representatives, to serve on the Digital Health Advisory Committee (the Committee) in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies effective with this notice. FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before December 11, 2023 will be given first consideration for membership on the Committee. Nominations received after December 11, 2023 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal (*https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm*) and selecting Academician/Practitioner from the dropdown menu (regardless of whether Academician/Practitioner accurately describes the nominee), or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: James Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–796–6313, *James.Swink@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill current vacancies on the Digital Health Advisory Committee. This notice does not include consumer and industry representative nominations. The Agency will publish two separate notices announcing the vacancy of a representative of consumer interests and a vacancy of representatives of interests of the device manufacturing industry.

I. General Description of the Committee Duties

The Committee provides advice on complex scientific and technical issues related to Digital Health Technologies (DHTs). This also may include advice on the regulation of DHTs, and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring,