the revised questionnaire) asks level-of-agreement questions very similar to the type of question the commenter proposes (*e.g.,* ''I counsel my patients differently when prescribing a product with a boxed warning.''). The revised questionnaire, however, excludes the open-ended Q30 in the revised questionnaire, in an effort to streamline the survey and reduce respondent burden.

(Comment 3p): [We] recommend adding an option ''I'm not sure/I don't know/I'm not familiar'' to Questions 2, 3, 4, 7, 8, 12, 14, 15, 23, 24, 25, 28, 29.

(Response 3p): FDA reviewed the survey and added an Unsure/Don't know option where we deemed appropriate: Qs 2, 3, 4, 28, 29. Questions 8 and 25 were removed. Q23 has an ''Other (specify)'' option where participants can elaborate if they are unable to choose an answer. For certain key questions that elicits respondents' opinions (Qs 7, 12, 14, 15, 24), we did not add Unsure/Don't know in order to encourage them to thoughtfully pick an answer. However, participants can proceed through the questions without providing an answer, if they wish.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest Screener	84	1	84	0.05 (3 minutes)	4
Pretest Informed Consent	50	1	50	0.05 (3 minutes)	2
Pretest Survey Completes	50	1	50	0.28 (17 minutes)	14
Main Survey Screener	1,927	1	1,927	0.05 (3 minutes)	96
Main Survey Informed Consent	1,156	1	1,156	0.05 (3 minutes)	58
Main Survey Completes	1,156	1	1,156	0.28 (17 minutes)	324
Total	4,423				498

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

II. References

The following references are on display with the Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are not available electronically at *https://www.regulations.gov* as these references are copyright protected.

1. Dusetzina, S.B., A.S. Higashi, E.R. Dorsey, et al., ''Impact of FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review.'' *Medical Care,* 50(6):466–478, 2012.
2. Briesacher, B.A., S.B. Soumerai, F. Zhang, et al., ''A Critical Review of Methods to Evaluate the Impact of FDA Regulatory Actions.'' *Pharmacoepidemiology Drug and Safety,* 22(9):986–994, 2013.
3. Morgan, M.G., et al., *Risk Communication: A Mental Models Approach.* Cambridge University Press, 2002.

Dated: June 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14377 Filed 7–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2020–N–1228]

Agency Information Collection Activities; Proposed Collection; Comment Request; Study of Multiple Indications in Direct-to-Consumer Television Advertisements

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 ''Study of Multiple Indications in Direct-to-Consumer Television Advertisements.''

DATES: Submit either electronic or written comments on the collection of information by September 4, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 4, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 4, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 2020–N–1228 for ''Study of Multiple Indications in Direct-to-Consumer Television Advertisements.'' 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.

- 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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.* The questionnaire is available upon request from *DTCResearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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.

Study of Multiple Indications in Direct-to-Consumer Television Advertisements—OMB Control Number 0910–NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the 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, in part, by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated, so that patients and health care 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 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 research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features, including content and format.

Because we recognize the strength of data and the confidence in the robust nature of the findings is 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

homepage, which can be found 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 website maintains information on studies we have conducted, dating back to a direct-to-consumer (DTC) survey conducted in 1999.

A number of prescription drugs are approved for multiple indications. These indications can be similar in certain respects (*e.g.,* diabetic peripheral neuropathy and fibromyalgia, which are both conditions that manifest in pain) or very different from one another (*e.g.,* diabetic peripheral neuropathy and general anxiety disorder). If a drug is approved for multiple indications, sponsors choose whether to promote only one of those indications in DTC television advertising, or multiple indications in the same television ad. We are unaware of any quantitative research that addresses how presenting multiple indications in one ad affects consumers' processing of drug information. Some research suggests that presenting more than one indication in a television ad, regardless of the similarity of the indications, may increase the cognitive load on consumers, thus decreasing their understanding of the drug's indications (Refs. 1 and3).

When more than one indication is presented, the similarity or dissimilarity of the indications may affect participants' ability to remember and understand the indications. If this is the case, it is not clear whether similarity would have a positive or negative effect in the multimodal context of a television ad (*e.g.,* Refs. 4 and 5).

This study will provide preliminary information on whether consumers face challenges when multiple indications are promoted in a single television ad. The study also will explore whether similarity of the indications affects participants' likelihood to recall and understand the indications, and whether its effect would be positive or negative.

We propose to test three types of fictional DTC television ads—one that promotes a single indication, one that promotes an indication plus a similar indication, and one that promotes an indication plus a dissimilar indication—in two different medical conditions (Table 1).

TABLE 1—STUDY DESIGN—1 × 3 FACTORIAL EXPERIMENT REPEATED IN TWO MEDICAL CONDITIONS

	Indication 1	Indication 1 plus a similar indication	Indication 1 plus a dissimilar indication
Study 1: Diabetic peripheral neuropathy (DPN)	DPN	DPN + fibromyalgia	DPN + general anxiety disorder.
Study 2: Rheumatoid arthritis (RA)	RA	RA + psoriatic arthritis	RA + leukemia.

We plan to conduct two pretests (one for each main study) and two main studies not longer than 20 minutes, administered via internet panel, to test the experimental manipulations and pilot the main study procedures. Participants will be randomly assigned to view one study ad and then complete a questionnaire that assesses recall and comprehension of the drug's benefits and risks, benefit and risk perceptions, attitudes, and behavioral intentions. We will also measure covariates such as demographics and health literacy. Taking into account prior research, it is our hypothesis that participants will be more likely to correctly recall and understand the first indication when it is presented alone, compared with when it is presented with a second (similar or dissimilar) indication. We will explore whether similarity of the indications affects participants' likelihood to recall and understand the indications. We will also explore the effects of the indication presentation on benefit and risk perceptions, attitudes toward the drug and the indication information, and intentions to look for more information and ask a doctor about the drug.

For all phases of this research, we will recruit adult volunteers 18 years of age or older. For Pretest 1 and Study 1, we will recruit participants who self-report being diagnosed with diabetes (N = 60 in Pretest 1 and N = 402 in Study 1). For Pretest 2 and Study 2, we will recruit participants who self-report being diagnosed with rheumatoid arthritis (N = 60 in Pretest 2 and N = 402 in Study 2). We will exclude individuals who work for the Department of Health and Human Services or work in the healthcare, marketing, or pharmaceutical industries. We will also exclude pretest participants from the main studies, and participants will not be able to participate in both Studies 1 and 2. With these sample sizes, we will have sufficient power to detect small-sized effects in Studies 1 and 2. For the burden estimate, we include an additional 10% over our target number of valid completes to account for some overage. FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Pretest 1 & 2 screener	264	1	264	.083 (5 min)	22
Pretest 1 & 2	132	1	132	.333 (20 min)	44
Main Study 1 & 2 screener	1,770	1	1,770	.083 (5 min)	147
Main Study 1 & 2	885	1	885	.333 (20 min)	295
Total					508

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

II. 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. Mayer, R.E., & Moreno, R. (2003), Nine Ways to Reduce Cognitive Load in Multimedia Learning. *Educational Psychologist, 38*(1), 43–52.
2. Mutlu-Bayraktar, D., Cosgun, V., & Altan, T. (2019), Cognitive Load in Multimedia Learning Environments: A Systematic Review. *Computers & Education,* 141, 103618.
3. Betts, K. R., Boudewyns, V., Aikin, K. J., Squire, C., Dolina, S., Hayes, J. J., & Southwell, B. G. (2018), 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.
4. Jiang, Y. V., Lee, H. J., Asaad, A., & Remington, R. (2016), Similarity Effects in Visual Working Memory, *Psychonomic Bulletin & Review,* 23(2), 476–482.
5. Oberauer, K., & Lange, E. B. (2008), Interference in Verbal Working Memory: Distinguishing Similarity-based Confusion, Feature Overwriting, and Feature Migration, *Journal of Memory and Language,* 58(3), 730–745.

Dated: June 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14375 Filed 7–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5841]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments (including recommendations) on the collection of information by August 5, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted *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 ''Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

OMB Control Number 0910–NEW

This notice announces the FDA information collection request from the OMB for a generic clearance that will allow FDA to use qualitative social/behavioral science data collection techniques (*i.e.,* individual in-depth interviews, small group discussions, focus groups, and observations) to understand stakeholders' perceptions, attitudes, motivations, and behaviors better regarding various issues associated with food and cosmetic products, dietary supplements, and animal food and feed. Understanding consumers', manufacturers', and producers' perceptions, attitudes, motivations, and behaviors plays an important role in improving FDA's communications impacting these various stakeholders and in assisting in the development of quantitative study proposals, complementing other important research efforts in the Agency.

FDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- the collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- the collections are noncontroversial;
- personally identifiable information (PII) is collected only to the extent necessary [1] and is not retained;
- information gathered will not be used for the purpose of substantially informing influential policy decisions; [2] and.
- information gathered will yield qualitative information; the collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the interview or moderator guide, screening questionnaire).

FDA will submit individual qualitative collections under this generic clearance to the OMB. Individual qualitative collections will also undergo review by FDA's institutional review board, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Description of Participants: Participants in this collection of information may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

In the **Federal Register** of February 10, 2020 (85 FR 7564), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although five comments

[1] For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

[2] As defined in OMB and Agency Information Quality Guidelines, ''influential'' means that ''an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.''