FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezutto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 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.

Guidance for Industry on Pharmacogenomic Data Submissions; OMB Control Number 0910–0557—Extension

The collection of information supports Agency guidance entitled, ''Guidance for Industry on Pharmacogenomic Data Submissions.'' The guidance provides recommendations to sponsors submitting or holding investigational new drug applications (INDs), new drug applications (NDAs), or biologics license applications (BLAs) on what pharmacogenomic data should be submitted to the Agency during the drug development process. Sponsors holding, and applicants submitting, INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the Agency data relevant to drug safety and efficacy (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under 21 CFR parts 312, 314, and 601 (approved under OMB control numbers 0910–0014 (part 312, INDs); 0910–0001 (part 314, NDAs and annual reports); and 0910–0338 (part 601, BLAs)), respectively.

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well-developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the Agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

In the **Federal Register** of March 17, 2017 (82 FR 14221), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment was received, however it was not responsive to the four information collection topics solicited in the notice and therefore is not addressed here.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS based on our experience with these submissions over the past few years, and on our familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process. In 2013, we received three VGDS. Since 2013, there have been no submission of VGDS; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually. We estimate each submission requires approximately 50 hours to prepare and submit to FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Voluntary Genomic Data Submissions	1	1	1	50	50

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

Dated: June 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12604 Filed 6–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1315]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 research entitled ''Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads.'' This study will examine how repetition and overwarning apply to the presentation of risks in the context of direct-to-consumer print advertising.

DATES: Submit either electronic or written comments on the collection of information by August 18, 2017.

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 August 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 18, 2017. 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–2017–N–1315 for ''Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads.'' 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.gpo.gov/fdsys/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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.* For copies of the questionnaire contact: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501–3520), 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.

Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads; 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 (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.

Section 502(n) of the FD&C Act (21 U.S.C. 352(n)) specifies that advertisements (ads) for prescription drugs and biological products must provide a true statement of information ''in brief summary'' describing the advertised product's ''side effects, contraindications and effectiveness.'' The prescription drug advertising regulations provide further clarification on the information to include in brief summary a true statement of information in brief summary relating to side effects, contraindications to include side effects, warnings, precautions, and

contraindications and include any such information under such headings as cautions, special considerations, important notes, etc. and effectiveness (21 CFR 202.1(e)(1)). The prescription drug advertising regulations also specify that the phrase *side effect and contraindication* refers to all of the categories of risk information contained in the required, approved or permitted product labeling written for health professionals, including the Warnings, Precautions, and Adverse Reactions sections (21 CFR 202.1(e)(3)(iii)). Ads must also ''present a fair balance between information relating to side effects and contraindications and effectiveness. . . .'' An ad must present true information relating to side effects and contraindications in comparable depth and detail with the claims for effectiveness or safety (21 CFR 202.1(e)(5)(ii)).

To fulfill the regulatory requirements for fair balance and the brief summary, sponsors have typically included risk information about the product in direct-to-consumer (DTC) print ads both in the main part of the ad where the product claims appear, and in a separate brief summary page. The section of the main ad where the risks appear is often referred to as the ''Important Safety Information'' (ISI). Including risks in both the ISI and the brief summary may have advantages. Some research has found that repetition of information improves recall, especially for older adults (Ref. 1). This might result in improved recall for risks that appear both in the ISI and brief summary. However, it is possible that risks appearing on the main page in the ISI may be more likely to be read than risks appearing in the brief summary. Based on FDA survey research, about 27 percent of consumers surveyed in 2002 reported reading half or more of the brief summary in DTC print ads (Ref. 2). In comparison, when asked how much of the ''main'' ad they read, about 78 percent reported reading ''all'' or ''almost all'' of the main body portion of the ad.

One potential downside to including the same warnings in both the ISI and again in the brief summary is the potential to overwarn consumers. Overwarning is the concept that individuals are exposed to so many warnings in the course of daily life that they are less likely to pay attention to any one particular warning (Ref. 3). In terms of presenting risk information, detailing too many risks may lead consumers to discount all risks, or miss the most important risk information. Similarly, habituation follows when readers see the same warning repeatedly. Upon seeing a particular warning repeatedly, consumers may cease to pay attention to it (Refs. 4 to 6). Even if a warning has features that make it noticeable, it still has the potential for habituation with repeated exposure (Ref. 5). Although researchers caution against habituation and overwarning, there appears to be little empirical research for the logical supposition that seeing repeated warnings will lead to increased selectivity and reduced attention by recipients over time. Of note, the Office of Prescription Drug Promotion (OPDP) is studying the issue of reduced risk information in the context of DTC TV ads (''Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements,'' OMB control number. 0910–0785).

OPDP plans to investigate, through empirical research, how repetition and overwarning apply to the presentation of risks in promotional prescription drug print pieces. We propose to test two levels of the ISI (short versus long) and the presence of the Brief Summary (absent versus present) in two different medical conditions (overactive bladder and rheumatoid arthritis). Figures 1 and 2 describe the study design. This will be investigated in DTC print ads for prescription drugs.

FIGURE 1—STUDY 1 DESIGN

	Brief summary	
Rheumatoid Arthritis: ISI ..... Short. Long.	No	Yes

FIGURE 2—STUDY 2 DESIGN

	Brief summary	
Overactive Bladder: ISI ..... Short. Long.	No	Yes

This project is designed to use eye tracking technology to determine how these risk presentations in DTC print ads are perceived. Eye tracking technology is an effective method to determine the extent to which consumers attend to risk information presented in DTC print ads. This technology allows researchers to unobtrusively detect and measure where a participant looks while viewing a print ad and for how long, and the pattern of their eye movements may indicate attention to and processing of information in the ad.

We plan to collect descriptive eye tracking data on participants' attention to the following: (1) The important safety information, (2) the brief summary, and (3) the indication and benefit claims. All participants will be 18 years of age or older. We will exclude individuals who are trained as healthcare professionals, or who work in pharmaceutical, advertising, or marketing settings because their knowledge and experiences may not reflect those of the typical consumer. We will also exclude individuals who have photosensitive epilepsy; use a medical device that is sensitive to infrared light; or wear bifocals, hard contact lenses, or colored contact lenses.

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance (ANOVA). With the sample size described in this document, we will have sufficient power to detect small-to-medium sized effects in the main study.

We plan to conduct one 60-minute pilot study with 40 participants and two 60-minute studies with 200 participants each (50 participants in each cell), for a total of 400 main study participants. The studies will be conducted in person in at least five different cities across the United States. The pilot study and main studies will have the same design and will follow the same procedure. Participants who self-identify as having one of the medical conditions of interest will be randomly assigned to one of four test conditions. In Study 1, the ad will be for a fictitious drug to treat rheumatoid arthritis. In Study 2, the ad will be for a fictitious drug to treat overactive bladder. After obtaining consent, we will explain the study procedure to participants and calibrate the eye tracking device. To collect eye tracking data, we will use an unobtrusive glasses-based real world eye tracker with a minimum speed of 50 Hertz. The test images will be presented on paper and sized similarly to how they would appear in print materials such as magazines. To simulate normal ad viewing, participants will view two ads. One of the ads will be the study ad. The non-study ad will be for a consumer product unrelated to health. Only eye tracking data from the study ad will be analyzed. Next, participants will complete a questionnaire that assesses risk perceptions, risk recall, efficacy perceptions, efficacy recall, and covariates such as demographics and health literacy. In the pilot study, participants will also answer questions as part of a debriefing interview to assess the study design and questionnaire.

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
Pilot screener	120	1	120	0.03 (2 minutes)	4
Study 1 screener	600	1	600	0.03 (2 minutes)	18
Study 2 screener	600	1	600	0.03 (2 minutes)	18
Completes, Pilot	40	1	40	1	40
Completes, Study 1	200	1	200	1	200
Completes, Study 2	200	1	200	1	200
Total					480

[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 in 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; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. McGuire, L.C., ''Remembering What the Doctor Said: Organization and Older Adults' Memory for Medical Information.'' *Experimental Aging Research,* 22, 403–428 (1996).
2. Aikin, K.J., J.L. Swasy, and A.C. Braman, ''Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Summary of FDA Survey Research Results'' (2004). Available at *http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/UCM152860.pdf.*
3. Warnings and Risk Communication (2005). Wogalter, M.S., D. DeJoy, and K.R. Laughery (Eds.). Philadelphia: Taylor & Francis, Inc.
4. Conzola, V.C., and M.S. Wogalter, ''A Communication-Human Information Processing (C–HIP) Approach to Warning Effectiveness in the Workplace.'' *Journal of Risk Research,* 4(4), 309–322; (2001).
5. Wogalter, M.S., and K.R Laughery, ''Warning! Sign and Label Effectiveness.'' *Current Directions in Psychological Science,* 5(2), 33–37; (1996).
6. Wogalter, M.S., T.L. Smith-Jackson, B.J. Mills, and C.S. Paine, ''The Effects of Print Format in Direct-to-Consumer Prescription Drug Advertisements on Risk Knowledge and Preference.'' *Drug Information Journal,* 36(3), 693–705, 2002.

Dated: June 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12600 Filed 6–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1779]

Agency Information Collection Activities; Proposed Collection; Comment Request; Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion

AGENCY: Food and Drug Administration, 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 research entitled ''Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion.''

DATES: Submit either electronic or written comments on the collection of information by August 18, 2017.

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 August 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 18, 2017. 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