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

<table>
<thead>
<tr>
<th>Information collection activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Hours per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary Genomic Data Submissions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
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:**
Jonna Lynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRAS Staff@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 (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)(iii)).

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
care 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
course 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**

<table>
<thead>
<tr>
<th>Brief summary</th>
<th>Rheumatoid Arthritis: ISI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Short. Long.</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

**FIGURE 2—STUDY 2 DESIGN**

<table>
<thead>
<tr>
<th>Brief summary</th>
<th>Overactive Bladder: ISI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Short. Long.</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

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:
## 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](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.


### Table 1—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot screener</td>
<td>120</td>
<td>1</td>
<td>120</td>
<td>0.03 (2 minutes)</td>
<td>4</td>
</tr>
<tr>
<td>Study 1 screener</td>
<td>600</td>
<td>1</td>
<td>600</td>
<td>0.03 (2 minutes)</td>
<td>18</td>
</tr>
<tr>
<td>Study 2 screener</td>
<td>600</td>
<td>1</td>
<td>600</td>
<td>0.03 (2 minutes)</td>
<td>18</td>
</tr>
<tr>
<td>Completes, Pilot</td>
<td>40</td>
<td>1</td>
<td>40</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>Completes, Study 1</td>
<td>200</td>
<td>1</td>
<td>200</td>
<td>1</td>
<td>200</td>
</tr>
<tr>
<td>Completes, Study 2</td>
<td>200</td>
<td>1</td>
<td>200</td>
<td>1</td>
<td>200</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>480</td>
</tr>
</tbody>
</table>

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

**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.

**ADDRESS:** 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](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](https://www.regulations.gov). Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://www.regulations.gov](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](https://www.regulations.gov).

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**Written/Paper Submissions**

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