

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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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, including each proposed extension of an existing 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.

Data To Support Drug Product Communications as Used by the Food and Drug Administration; OMB Control Number 0910-0695—Extension

Testing of messages in advance of a communication campaign provides an important role in improving FDA communications. The methods to be employed include individual indepth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews. The qualitative

methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and have two major purposes: To obtain information that is useful in formulating policies and regulatory decisions and for developing variables and measures for formulating the basic objectives of risk communication campaigns, and to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences.

FDA will use these methods to test and help refine messages and other communications but will generally conduct further research before making important decisions. FDA will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or health care professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, medication guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products, and consumer and professional education. Annually, FDA projects about 45 communication studies using the variety of test methods listed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (in hours) | Total hours |
|--------------------------|-----------------------|------------------------------------|------------------------|--|-------------|
| Interviews/Surveys | 19,822 | 1 | 19,822 | 0.24 (14 minutes) | 4,757 |

¹ 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.
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BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA-2010-N-0536]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Pharmacogenomic Data Submission

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.

DATES: Fax written comments on the collection of information by July 19, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0557. Also include the FDA docket number found in brackets in the heading of this document.

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.
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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