



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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 oir_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, PRASStaff@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 Burden¹

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Voluntary Genomic Data Submissions	1	1	1	50	50

¹There 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: 6/16/2017 8:45 am; Publication Date: 6/19/2017]