

Dated: October 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0190]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Formula Requirements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Infant Formula Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, e-mail: [Juanmanuel.Vilela@fda.hhs.gov](mailto:Juanmanuel.Vilela@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 10, 2010 (75 FR 48350), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0256. The approval expires on October 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0098]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Evaluation of Potential Data Sources for the Sentinel Initiative

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Evaluation of Potential Data Sources for the Sentinel Initiative" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, [Jonnalynn.capezzuto@fda.hhs.gov](mailto:Jonnalynn.capezzuto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 4, 2009 (74 FR 45858), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0657. The approval expires on February 28, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0536]

#### Agency Information Collection Activities; Proposed Collection; Comment Request, Guidance for Industry on Pharmacogenomic Data Submissions; Extension

**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 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection resulting from recommendations to sponsors submitting or holding investigational new drug applications (INDs), new drug applications (NDAs), or biologic licensing applications (BLAs) on what pharmacogenomic data should be submitted to the agency during the drug development process.

**DATES:** Submit either electronic or written comments on the collection of information by January 3, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@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.

**Guidance for Industry on Pharmacogenomic Data Submissions (OMB Control Number 0910-0557—Extension)**

The guidance provides recommendations to sponsors submitting or holding INDs, NDAs, or 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 (§§ 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 parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910-0014 (part 312—INDs); 0910-0001 (part 314—NDAs and annual reports); and 0910-0338 (part 601—BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decision-making, 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.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with this guidance over the past few years, and on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately seven sponsors will submit approximately one VGDS and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Voluntary Genomic Data Submissions Total .....	7	1	7	50	350

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection.

Dated: October 29, 2010.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0381]

**Generic Drug User Fee; Notice of Public Meeting; Reopening of the Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until December 6, 2010, the comment period

for the notice of public meeting entitled Generic Drug User Fee; Public Meeting; Request for Comments, published in the **Federal Register** of August 9, 2010 (75 FR 47820). In that notice, FDA announced a public meeting that took place on September 17, 2010, to gather stakeholder input on the development of a generic drug user fee program. FDA is reopening the comment period to permit public consideration of late-received comments and to provide an opportunity for all interested parties to provide information and share views on the matter.

**DATES:** Submit either electronic or written comments by December 6, 2010.