

Dated: October 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-27850 Filed 11-3-10; 8:45 am]

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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