

biological sampling of the biological parents of the child participant (blood only). Minor changes to some of the self administered questionnaires and the telephone interview include clarification of instructions to the

respondent and clarifying specific questions to make the instruments easier to complete and further improve data quality. The only study design change that is being proposed is to expand the eligible study participant

birth date range from September 1, 2003–August 31, 2005 to September 1, 2003–August 31, 2006.

There is no cost to respondents other than their time. The total estimated annualized burden is 4,948 hours.

## ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Responses per respondent	Avg. burden per response (in hours)
Parent .....	Response Card .....	2,458	1	10/60
Parent .....	Invitation packet .....	1,008	1	30/60
Parent .....	Questionnaire packet .....	347	1	3.5
Parent .....	Caregiver Interview packet .....	402	1	1.5
Parent .....	Follow-up telephone call packet .....	347	3	20/60
Parent and Child .....	Biosample packet .....	1,041	1	40/60
Parent and Child .....	Blood Draw .....	966	1	15/60
Child .....	Clinic Visit—control children packet .....	214	1	1
Parent .....	Clinic Visit—control parent .....	80	1	45/60
Parent .....	Control parent consent form .....	214	1	10/60
Child .....	Clinic Visit—Case children packet .....	107	1	1.5
Parent .....	Clinic Visit—Case parent packet .....	107	1	3.5
Parent .....	Medical Record Abstraction .....	347	5	3/60

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA–2009–N–0483]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device User Fee Cover Sheet—Form FDA 3601**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Medical Device User Fee Cover Sheet—Form FDA 3601” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 19, 2010 (75 FR 2866), 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 0910–0511. 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: April 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–2009–N–0486]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry, Food and Drug Administration, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing

that a collection of information entitled “Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 19, 2010 (75 FR 2874), 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 0910–0508. 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: April 29, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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