TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Amendments/Resubmissions	356h	314	17	5,338	20	106,760
TOTAL						341,697

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirements under §§ 610.9(a), 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).
[3] The reporting requirements under §§ 640.70(a), 640.74(b)(3) and (4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a), (b), and (c), 660.35(a), (c through g), and (i through m), 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.65.
[4] The reporting requirements under §§ 610.9(a), 600.15(b), 610.11(g)(2), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 640.120, and 680.1(d) are included in the estimate under § 601.12(b).
[5] The reporting requirements under §§ 610.9(a), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(3).

Under table 2 of this document, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER (Adverse Event Reports) system.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.91(b)(2)(iii)	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13815 Filed 6–8–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Grant Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Noncompetitive Program Extension Supplemental Awards.

SUMMARY: HRSA will be issuing non-competitive supplemental funding under the Maternal Child and Health Bureau's Family to Family Health Information Centers Program. This will provide feasible time for the Maternal and Child Health Bureau (MCHB) to align fiscal resources and programmatic goals as outlined in changes that emerged as a result of enactment of the Patient Protection and Affordable Care Act (Pub. L. 111–148) with the least disruption to the States, communities, and constituencies that currently receive assistance and services from these grantees.

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Award: The 30 incumbent grantees (*see* list below).

Amount of the Non-Competitive Supplemental Funding: $97,500 per grantee.

Authority: Section 501(c)(1) of the Social Security Act, as amended.

CFDA Number: 93.110.

Project Period: June 1, 2010 through May 31, 2011 for a total of 12 months.

Justification for the Exception to Competition

The program provides grants to family-run/staffed organizations to ensure families of children with special health care needs have access to adequate information about health and community resources to allow informed decisions around their children's health care. Family to Family Health Information Centers (F2F HICs) were originally authorized under the Family Opportunity Act as part of the Budget Deficit Reduction Act of 2005; Pub. L. 109–171. Congress specified that there be a family-run/staffed center in each State and the District of Columbia by June 2009. These centers, among other tasks, were to assist families of children with special health care needs to make informed choices about health care in order to promote good treatment decisions, cost effectiveness and improved health outcomes by providing information and educational opportunities for families, their health professionals, schools, and other appropriate entities. Awards were staggered based upon available funding with 30 grantees awarded in 2007 with project periods ending May 31, 2010. As the end of their project period quickly approached and continued funding was not provided in the President's Budget for fiscal year (FY) 2010, MCHB prepared for closeout of the program.

Section 5507 of the Patient Protection and Affordable Care Act (the Affordable Care Act) extended the F2F HICs through FY 2012. Therefore, the MCHB will extend the project periods of the 30 aforementioned grants into FY 2011. This will provide sufficient fiscal resources to continue programmatic activities as outlined in legislation with the least disruption to the States, communities, and the MCHB constituencies that currently receive assistance and services from these grantees. The MCHB will also delay the competition for these grants until FY 2011 to ensure continuity of funding for all eligible entities, with no eligible entity being adversely impacted by the extension.

FOR FURTHER INFORMATION CONTACT: LaQuanta Person, Project Officer, Integrated Services Branch, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18A–18, Rockville, MD 20857; 301.443.2370; *lperson@hrsa.gov.*

MATERNAL AND CHILD HEALTH BUREAU SELECTED GRANT PROGRAMS

[Extensions with funding]

Grantee/organization name	State	FY 2009 authorized funding level	Revised project end date
Raising Special Kids	AZ	$95,700	31–May–11.
Support for Families of Children w/Disabilities	CA	95,700	31–May–11.
Family Voices of District of Columbia, Inc.	DC	95,700	31–May–11.
Family Institute for Family Involvement	FL	95,700	31–May–11.
Parent to Parent of Georgia, Inc.	GA	95,700	31–May–11.
Hawaii Pediatric Association Research & Education Foundation	HI	95,700	31–May–11.
The Arc of Illinois	IL	95,700	31–May–11.
About Special Kids, Inc.	IN	95,700	31–May–11.
Bayou Land Families Helping Families	LA	95,700	31–May–11.
Federation for Children With Special Needs	MA	95,700	31–May–11.
The Parent's Place of MD	MD	95,700	31–May–11.
Maine Parent Federation	ME	95,700	31–May–11.
Pacer Center Inc.	MN	95,700	31–May–11.
University of Southern Mississippi	MS	95,700	31–May–11.
Exceptional Children's Assistance Center	NC	95,700	31–May–11.
Family Voices of North Dakota, Inc	ND	95,700	31–May–11.
PTI Nebraska	NE	95,700	31–May–11.
Statewide Parent Advocacy Network of New Jersey	NJ	95,700	31–May–11.
Parents Reaching Out To Help	NM	95,700	31–May–11.
Family TIES of Nevada, Inc	NV	95,700	31–May–11.
Parent to Parent of NYS	NY	95,700	31–May–11.
Oregon Family Support Network	OR	95,700	31–May–11.
Parent Education & Advocacy Leadership Center	PA	95,700	31–May–11.
Rhode Island Parent Information Network, Inc.	RI	95,700	31–May–11.
South Dakota Parent Connection, Inc.	SD	95,700	31–May–11.
Tennessee Disability Coalition	TN	95,700	31–May–11.
Texas Parent to Parent	TX	95,700	31–May–11.
Utah Parent Center	UT	95,700	31–May–11.
Parent to Parent of Vermont	VT	95,700	31–May–11.
The Arc Wisconsin Disability Association	WI	95,700	31–May–11.

Dated: June 3, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–13788 Filed 6–8–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0277]

Draft Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Draft Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents." The draft guidance is intended to help small entities comply with the final regulations restricting the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 31, 2010.

ADDRESSES: The draft guidance for industry entitled "Draft Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" is available on the Internet at *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*, or a paper copy may be ordered free of charge by calling 1–877–287–1373.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kathleen K. Quinn, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 240–276–1717, *Kathleen.Quinn@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111–31; 123 Stat. 1776) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FFDCA) and providing FDA with the authority to regulate tobacco products. Section 102 of the Tobacco Control Act requires FDA to publish final regulations regarding cigarettes and smokeless tobacco which are identical in their provisions to the regulations promulgated by FDA in 1996 (1996 final regulations) on August 28, 1996 (61 FR 44396), with certain specified exceptions. In the **Federal Register** of March 19, 2010 (75 FR 13225), FDA published its final regulations entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To