

## EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Total .....	1,800,000	900,000

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: May 28, 2010.

**Carolyn M. Clancy,**  
*Director.*

[FR Doc. 2010-13728 Filed 6-8-10; 8:45 am]

BILLING CODE 4160-90-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0019]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567**

**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 July 9, 2010.

**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 e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0338. Also include the FDA 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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567 (OMB Control Number 0910-0338)—Extension**

Under Section 351 of the Public Health Services Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as

prescribed by regulations in part 601 (21 CFR Part 601).

Section 130(a) of the Food and Drug Administration Modernization Act (Public Law 105-115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of additional collection of information requirements follows.

Section 601.2(a) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65. The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.

Section 601.5(a) requires a manufacturer to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the manufacturer to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12 (a)(2) requires, generally, that the holder of an approved BLA must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant

must promptly revise all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5) requires the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under 601.12(f)(4) in table 1 of this document.

Sections 601.12(b)(1) and (b)(3), (c)(1) and (c)(3), and (c)(5), and (d)(1) and (d)(3) require applicants to follow specific procedures to submit information to FDA of any changes, in the product, production process, quality controls, equipment, facilities, or responsible personnel established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship of the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (b)(3) in table 1 of this document.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures to report certain labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes.

Under section 601.14, the content of labeling required in § 201.100(d)(3) must be in electronic format and in a form that FDA can process, review, and archive. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f). The burden estimate for § 601.14 is minimal and included in the estimate under §§ 601.2(a) (BLAs) and 601.12(f)(1), (f)(2), and (f)(3) (labeling supplements and annual reports) in table 1 of this document.

Section 601.45 requires applicants of biological products for serious or life-threatening illnesses to submit to the agency for consideration, during the

pre-approval review period, copies of all promotional materials, including promotional labeling as well as advertisements.

In addition to §§ 601.2 and 601.12, there are other regulations in 21 CFR parts 640, 660, and 680 that relate to information to be submitted in a license application or supplement for certain blood or allergenic products as follows: §§ 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), 660.51(a)(4), 680.1(b)(2)(iii), and 680.1(d). In table 1 of this document, the burden associated with the information collection requirements in these regulations is included in the burden estimate for §§ 601.2 and/or 601.12. A regulation may be listed under more than one subsection of § 601.12 due to the type of category under which a change to an approved application may be submitted.

There are also additional container and/or package labeling requirements for certain licensed biological products including: § 640.70(a) for Source Plasma; § 640.74(b)(3) and (4) for Source Plasma Liquid; § 640.84(a) and (c) for Albumin; § 640.94(a) for Plasma Protein Fraction; § 660.2(c) for Antibody to Hepatitis B Surface Antigen; § 660.28(a), (b), and (c) for Blood Grouping Reagent; § 660.35(a), (c through g), and (i through m) for Reagent Red Blood Cells; § 660.45 for Hepatitis B Surface Antigen; and § 660.55(a) and (b) for Anti-Human Globulin. The burden associated with the additional labeling requirements for submission of a license application for these certain biological products is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.65 or § 809.10. Therefore, the burden estimates for these regulations are included in the estimate under §§ 610.60 through 610.65 in table 1 of this document. The burden estimates associated with § 809.10 are approved under OMB Control No. 0910-0485.

Section 601.25(b) requests interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products that have been licensed prior to July 1, 1972. Section 601.26(f) requires that licensees submit to FDA a written statement intended to show that studies adequate and appropriate to resolve the questions raised about a biological product have been undertaken for a product if designated as requiring further study under the reclassification procedures. Under § 601.25(b), FDA estimates no PRA burden for this regulation, and therefore this regulation is not included

in table 1 of this document. Under section 601.26(f), FDA estimates no burden for this regulation since there are no products designated to require further study and none are predicted in the future. However, FDA is using an estimate of 1 for calculation purposes. Based on the possible reclassification of a product, the labeling for the product may need to be revised, or a manufacturer, on its own initiative, may deem it necessary for further study. As a result, any changes to product labeling would be reported under the appropriate subsection of § 601.12.

Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a) until after licensing the product for use in adults. Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a) with adequate justification. The burden estimates for § 601.27(a) are included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.28 requires sponsors of licensed biological products to submit the information in § 601.28(a), (b), and (c) to the Center for Biologics Evaluation and Research (CBER) or Center for Drug Evaluation and Research (CDER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, on or behalf of, the applicant. If the postmarketing studies were required or agreed to, the status of these studies is to be reported under § 601.70 rather than under this section.

Sections 601.33 through 601.35 clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals. The burden estimates for §§ 601.33 through 601.35 are included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.70 (b) requires each applicant of a licensed biological product to submit annually a report to FDA on the status of postmarketing studies for each approved product application. Each annual postmarketing status report must be accompanied by a completed transmittal Form FDA 2252 (Form FDA 2252 approved under OMB No. 0910-0001). Under § 601.70(d), two copies of the annual report shall be submitted to FDA.

Section 601.91 through 601.94 concerns biological products for which human efficacy studies are not ethical or feasible. Section 601.91(b)(3) requires applicants to prepare and provide labeling with relevant information to patient or potential patient for biological products approved under the subpart when human efficacy studies are not ethical or feasible (or based on evidence of effectiveness from studies in animals). Section 601.93 provides that biological products approved under this subpart are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products. Section 601.94 requires applicants under this subpart to submit to the agency for consideration during preapproval review period copies of all promotional materials including promotional labeling as well as advertisements.

Under § 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under 21 CFR part 600 (OMB Control No. 0910-0308). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB Control No. 0910-0308).

Section 610.9(a) requires the applicant to present certain information, in the form of a license application or supplement to the application, for a modification of any particular test method or manufacturing process or the conditions which it is conducted under the biologics regulations. The burden estimate for § 610.9(a) is included in the estimate under §§ 601.2(a) and 601.12(b) and (c) in table 1 of this document.

Section 610.11(g)(2) provides that a manufacturer of certain biological products may request an exemption from the general safety test (GST) requirements contained in this subpart. Under § 610.11(g)(2), FDA requires only those manufacturers of biological products requesting an exemption from the GST to submit additional information as part of a license application or supplement to an approved license application. Therefore, the burden estimate for § 610.11(g)(2) is included in the estimate under §§ 601.2(a) and 601.12(b) in table 1 of this document.

Section 640.120 requires licensed establishments to submit a request for an exception or alternative to any requirement in the biologics regulations regarding blood, blood components, or blood products. A request for an exception or alternative must be submitted in accordance with § 601.12; therefore the burden estimate for § 640.120 is included in the estimate under § 601.12(b) in table 1 of this document.

Section 680.1(c) requires manufacturers to update annually their license file with the list of source materials and the suppliers of the materials. Section 680.1(b)(3)(iv) requires manufacturers to notify FDA when certain diseases are detected in source materials.

Sections 600.15(b) and 610.53(d) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 606.110(b) requires the submission of a request for approval to perform plasmapheresis of donors who do not meet certain donor requirements for the collection of plasma containing rare antibodies. Under §§ 600.15(b), 610.53(d), and 606.110(b), a request for an exemption or modification to the requirements would be submitted as a supplement. Therefore, the burden hours for any submissions under §§ 600.15(b), 610.53(d), and 606.110(b) are included in the estimates under § 601.12(b) in table 1 of this document.

In July 1997, FDA revised Form FDA 356h "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use" to harmonize application procedures between CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may

be eliminated. The form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for nonbiological product submissions to CDER using FDA Form 356h are approved under OMB Control No. 0910-0001.

Form FDA 2567 "Transmittal of Labels and Circulars" is used by manufacturers of licensed biological products to submit labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. The labeling information is submitted with the form for license applications, supplements, or as part of an annual report. Form FDA 2567 is also used for the transmission of advertisements and promotional labeling. Form FDA 2567 serves as an easy guide to assure that the manufacturer has provided the information required for expeditious handling of their labeling by CBER. For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by CDER. In August of 1998, FDA revised and harmonized Form FDA 2253 so the form may be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services); and helps ensure that the submission is complete. Form FDA 2253 is approved under OMB Control No. 0910-0001.

Under table 1 of this document, the number of respondents is based on the estimated annual number of manufacturers that submitted the required information to FDA or the number of submissions FDA received in fiscal year (FY) 2008. Based on information obtained from FDA's database systems, there are an estimated 301 licensed biologics manufacturers. The total annual responses are based on the estimated number of submissions (i.e., license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) for a particular product received annually by FDA. Based on previous estimates, the rate of submissions is not expected to change

significantly in the next few years. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary.

Under §§ 601.2 and 601.12, the estimated hours per response are based on the average number of hours to submit the various submissions. The estimated average number of hours is based on the range of hours to complete a very basic application or supplement and a complex application or supplement.

Under section 601.6(a), the total annual responses are based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension, and provide FDA of such notification. The number of respondents is based on the

estimated annual number of suspensions of a biologic license.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. Based on information obtained from FDA's database system, there were an estimated 4,452 submissions of advertising and promotional labeling. FDA estimates that approximately 15% of those submissions were received with Form FDA 2567 and 85% were received with Form 2253.

Under §§ 601.28 and 601.70(b), FDA estimates that it takes an applicant approximately 24 hours (8 hours per study x 3 studies) annually to gather, complete, and submit the appropriate information for each postmarketing status report (approximately two to four studies per report) and the accompanied transmittal Form FDA 2252. Included in these 24 hours is the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

Under §§ 601.91 through 601.94, FDA expects to receive very few applications

for these products; however, for calculation purposes, FDA is estimating the annual submission of one application. Under §§ 601.93(b)(3) and 601.94, FDA estimates 240 hours for a manufacturer of a new biological product to develop patient labeling, and to submit the appropriate information and promotional labeling to FDA. The majority of the burden for developing the patient labeling is included under the reporting requirements for § 601.94, therefore minimal burden is calculated for providing the guide to patients under § 601.91(b)(3).

There were a total of 5,338 amendments to an unapproved application or supplement and resubmissions submitted using Form FDA 356h.

In the **Federal Register** of January 26, 2010 (75 FR 4081), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on this information collection request.

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

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

21 CFR Section	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.2(a) <sup>2</sup> , 610.60 through 610.65 <sup>3</sup>	2567/356h	23	2	46	860	39,560
601.5(a)	NA	11	3	33	20 minutes	11
601.6(a)	NA	1	21	21	20 minutes	7
601.12(a)(5)	NA	802	9	7,218	1	7,218
601.12(b)(1)/(b)(3)/(e) <sup>4</sup>	356h <sup>2</sup>	166	5	830	80	66,400
601.12(c)(1)/(c)(3) <sup>5</sup>	356h <sup>2</sup>	141	5	705	50	35,250
601.12(c)(5)	356h <sup>2</sup>	42	5	210	50	10,500
601.12(d)(1)/(d)(3)/(f)(3) <sup>7</sup>	356h <sup>2</sup>	246	3	738	23	16,974
601.12(f)(1) <sup>6</sup>	2567	112	2	224	40	8,960
601.12(f)(2) <sup>6</sup>	2567	53	3	159	20	3,180
601.12(f)(4)/601.45	2567/2253	42	106	4,452	10	44,520
601.26(f)	NA	1	1	1	1	1
601.27(b)	NA	6	1	6	24	144
601.27(c)	NA	10	1	10	8	80
601.70(b) and (d)/601.28	2252	39	2	78	24	1,872
601.91(b)(3), 601.94	NA	1	1	1	240	240
680.1(c)	NA	9	1	9	2	18
680.1(b)(3)(iv)	NA	1	1	1	2	2

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—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
<b>TOTAL</b>						<b>341,697</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.  
<sup>2</sup> 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).  
<sup>3</sup> 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.  
<sup>4</sup> 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).  
<sup>5</sup> 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).  
<sup>6</sup> The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).  
<sup>7</sup> 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<sup>1</sup>

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

<sup>1</sup> 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*.