of how GDUFA program resources are used. This is described in section VI(B).

The Agency would also expand its performance reporting by publishing robust monthly, quarterly and annual program performance metrics, as described in section VI(C). Enhanced performance reporting would enable Congress, the regulated industry, patient and consumer groups, and other stakeholders to better gauge the generic drug program's performance.

G. Enhancements to Fee Structure and Related Mechanisms To Provide Small Business Relief and Increase Predictability, Stability, and Efficiency

The proposed GDUFA II fee structure was designed to provide FDA with predictable, adequate funding for its human generic drug review programs, divide fee responsibilities equitably across different segments of the industry, and provide for small business considerations in a number of ways.

GDUFA II will be funded at a level commensurate with the amount of work associated with incoming ANDAs, since ANDAs are the primary workload driver of GDUFA. In order to provide a more predictable revenue base, GDUFA II will include an annualized ''program fee'' for ANDA holders. This annual fee will help offset the fluctuations in application fees from 1 year to another. An ANDA sponsor will pay a fee based on the total number of approved ANDAs that it and its affiliates own. ANDA sponsors will be split into three tiers based on ANDA ownership. The proposed tier cutoffs were determined by industry and are meant to reflect a firm's size, position in the market, and reliance on the program. With the introduction of the program fee, FDA has eliminated the fee for PASs.

In addition to program fees based on total ANDA ownership, the proposed fee structure includes two other distinct considerations for small businesses. First, under GDUFA I, a facility would pay an annual fee if it was listed in an ANDA, regardless of whether it was listed in any approved ANDAs. As a result, a facility that is listed only in pending applications is charged an annual GDUFA fee even though it has no generic drug revenue stream. Under GDUFA II, no facility or ANDA sponsor would be charged an annual fee until an ANDA in which it is listed is approved. Second, the proposed structure adds a facility category for contract manufacturing organizations (CMOs). CMOs are generally small businesses that are hired by ANDA sponsors to manufacture their generic drugs. Alternatively, some ANDA sponsors manufacture their own drugs. Under the GDUFA II fee structure, CMOs will pay one-third the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own.

The full descriptions of these proposed recommendations will be posted prior to the public meeting on FDA's Web site at *www.fda.gov/gdufa*.

IV. Purpose and Scope of the Meeting

If you wish to attend this meeting, please email your registration information to Derek Griffing (see **FOR FURTHER INFORMATION CONTACT**) by October 7, 2016. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and is on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Derek Griffing (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

The meeting will include a presentation by FDA and a series of invited panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated industry). We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

If you wish to present at the meeting, please include your presentation materials along with your registration information to Derek Griffing (see **FOR FURTHER INFORMATION CONTACT**) by October 7, 2016. Early requests for oral presentations are recommended due to possible space and time limitations. FDA will accommodate as many requests for oral presentations as possible and will do so on a first-come, first-served basis. The time allotted for presentations may depend on the number of persons who wish to speak. Those requesting to present will receive confirmation once they have been accepted. Onsite requests for oral presentations on the day of the meeting will be based on time and space availability. If the entire meeting time is not needed, FDA may end the public meeting early.

V. Transcript Request

Please be advised that as soon as a transcript is available, it will be accessible at *www.fda.gov/gdufa* and in this docket at *http://www.regulations.gov*.

It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov*.

Dated: September 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23111 Filed 9–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2610]

A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket'' that appeared in the **Federal Register** of September 19, 2016 (81 FR 64177). The document announced the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (such as academic researchers, regulated industries, consortia, and patient groups) on a list of biomarkers that were used as outcomes to develop FDA-approved new molecular entities (NMEs) and New Biological Therapeutics from October 2007 to December 2015. The document was published without an active Web link. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring MD 20993–0002, 301–796–9115, *lisa.granger@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, September 19, 2016, in FR Doc. 2016–22470, on page 64178 the following correction is made:

On page 64178, in the second column, in the last sentence of the first paragraph under Section I, Background, ''Biomarkers Used as Outcomes in Development of FDA-Approved Therapeutics (October 2007 to December 2015)'' is corrected to read ''*http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm483052.htm*''.

Dated: September 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23106 Filed 9–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supplement for Zika Response, a Single-Award Deviation From Competition Requirements for the National Center for Medical Home Implementation Cooperative Agreement

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

ACTION: Notice.

SUMMARY: HRSA announces the award of a supplement in the amount of $350,000 for the National Center for Medical Home Implementation (NCMHI) cooperative agreement. The purpose of the NCMHI cooperative agreement is to support a national resource and assistance effort to implement and spread the medical home model to all children and youth, particularly children with special health care needs (CSHCN), children who are vulnerable and/or medically underserved, and pediatric populations served by state public health programs, the Maternal and Child Health Bureau (MCHB), and HRSA. The supplement will permit the American Academy of Pediatrics (AAP), the cooperative agreement awardee, during the budget period of July 1, 2016–June 30, 2017, to enhance their capacity to provide technical assistance and health professional education to increase the clinical expertise of pediatric health care professionals, including safety net providers, to more effectively serve as the medical home and provide family-centered, comprehensive, coordinated, and culturally-effective care for Zika-affected children and their families.

FOR FURTHER INFORMATION CONTACT: Marie Y. Mann, MD, MPH, FAAP, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W61, Rockville, Maryland 20857; *MMann@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The American Academy of Pediatrics.

Amount of Non-Competitive Awards: $350,000.

Period of Supplemental Funding: 7/1/2016–6/30/2017.

CFDA Number: 93.110.

Authority: Social Security Act, Title V, sections 501(a)(1)(D) and 501(a)(2), (42 U.S.C. 701(a)(1)(D) and 701(a)(2))

Justification: Zika virus infection during pregnancy dramatically increases the risk of birth defects. Microcephaly has been linked to Zika virus infection during pregnancy, and the extent of other possible birth defects is unclear. As of August 25, 2016, there are 624 pregnant women in the 50 states and the District of Columbia reported to have the Zika virus infection. In Puerto Rico, over 600 pregnant women have been reported to have the Zika virus infection as a result of exposure to the Zika virus during pregnancy. However, pediatric specialty expertise to care for their babies is limited. Currently, no network exists to link providers caring for these patients with those who have relevant expertise or experience in managing infants and children of women exposed to Zika virus during pregnancy. Discussions of developmental screening, clinical management, and family support approaches will help clinicians serving this population, thereby increasing access to well-coordinated, family-centered care and management in a medical home for children and families impacted by Zika-related complications.

The purpose of the NCMHI cooperative agreement is to support a national resource and assistance effort to implement and spread the medical home model to all children and youth, particularly CSHCN, children who are vulnerable and/or medically underserved, and pediatric populations served by state public health programs, MCHB, and HRSA. In 2013, following objective review of its competitive application, HRSA awarded the NCMHI cooperative agreement to AAP, a nonprofit, tax-exempt organization under Internal Revenue Code 501(c)(3).

This supplement to the NCMHI cooperative agreement provides technical assistance and education, including tele-mentoring, to clinicians providing care for children who are or may be impacted by Zika at HRSA-supported health centers and elsewhere within the United States (including U.S. territories and jurisdictions). Using the tele-mentoring technology, clinicians will team with specialists elsewhere to provide clinicians with the tools and resources to improve care delivery within the medical home, thereby increasing the sustainability of the medical home model for children affected by Zika. Though available to all clinicians, technical assistance and education will be directed primarily toward pediatric primary care physicians in areas at high-risk for Zika and toward clinicians operating in health centers supported by HRSA's Bureau of Primary Health Care. These activities will provide critical knowledge to health care professionals, including safety net providers, to more effectively serve as the medical home for children affected by Zika and their families.

Grantee/organization name	Grant No.	State	FY 2016 authorized funding level	FY 2016 estimated funding for this supplement
The American Academy of Pediatrics	U43MC09134	IL	$1,300,031	$350,000