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

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1040.30(c)(2)	N/A	7	1	7	1	7
1050.10(d)(1) through (d)(4) and (f)(1) through (f)(2)(iii)	N/A	10	1	10	56	560
Total Annual Reporting Burden						88,435

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	0.12	228,459
1002.40 and 1002.41	2,950	49.2	145,140	0.05	7,257
1020.30(g)	22	1	22	0.5	11
1040.10(a)(3)(ii)	40	1	40	1.0	40
Total					235,767

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

The burden estimates were derived by consultation with FDA and industry personnel, and are based on actual data collected from industry. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry.

The following information collection requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); 1005.21(a) through (c), and 1005.22(b). These requirements apply to the collection of information during the conduct of general investigations or audits (5 CFR 1320.4(b)).

The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: February 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–4002 Filed 2–25–10; 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 providing extensions with funds ranging from 5 to 10 months to program grantees for the following programs in order to bring these programs into alignment with changes resulting from HRSA's Maternal and Child Health Bureau's developing strategic plan and the Early Learning and Development Initiative of the HHS and Department of Education. The programs are:

- Alliance for Information in Maternal and Child Health (AIM)
  - Improving Understanding of MCH—10 grants
  - Partnerships to Promote MCH—5 grants
- AIM Policy Center—1 grant
- Mental Health and Schools Resource Centers—2 grants
- Public Policy Analysis and Education Center for Early Childhood—1 grant
- National Healthy Child Care America Program
  - National Training Institute for Health Consultants—1 grant
  - Child Care Health Partnership Program—1 grant
  - Resource Center for Childcare Health and Safety—1 grant
- National Sudden and Unexpected Infant/Child Death and Pregnancy Loss Centers—3 grants

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Award

The intended recipients are the incumbent grantees. They are either national membership organizations whose members impact maternal and child health programming or institutions of higher learning. They share a common purpose of providing education and technical assistance to either their individual members or State and community Maternal and Child Health programs.

Authority: Section 501(a) (3) of the Social Security Act, as amended

CFDA Number: 93.110.

Project Period: The period of supplemental support is from the grantee's original project end date

through January 31, 2011. The periods range from 5 to 10 months.

Grantees and Amount of the Awards: See listing below.

HRSA Competition Name and Announcement Number / Organization Name	Grant number	Project period	FY 2009 authorized funding level	Revised project end date	Supplemental funding
Alliance for Information on Maternal and Child Health (AIM) Improving Understanding of Maternal and Child Health and Health Care Issues, HRSA–05–079					
National Conference of State Legislatures.	G96MC04443	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
National Conference of State Legislatures.	G96MC04444	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
Association of State and Territorial Health Officials.	G96MC04445	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
National Institute for Health Care Management.	G96MC04446	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
National Business Group on Health	G96MC04447	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
Grantmakers in Health	G96MC04448	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
National Association of County and City Health Officials.	G96MC04449	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
National Governors Association	G96MC04450	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
American Bar Association	G96MC04451	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
Grantmakers for Children, Youth and Families.	G96MC04452	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
Alliance for Information on Maternal and Child Health (AIM) Partnerships to Promote Maternal and Child Health, HRSA–05–076					
Family Voices, Inc.	G97MC04453	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
Today's Child Communications, Inc.	G97MC04454	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
American Academy of Pediatric Dentistry.	G97MC04455	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
National Healthy Start Association, Inc.	G97MC04488	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
American Academy of Pediatrics	G97MC06336	1–May-05—30–Apr-10	$200,000	31–Jan-11	$150,000
Alliance for Information on Maternal and Child Health (AIM) Child and Adolescent Policy Support Center, HRSA–07–041					
The Regents of the University of California.	U45MC08263	1–Jul-07- 30–Jun-10	$300,000	31–Jan-11	$175,000
School Mental Health Program and Policy Analysis Centers, HRSA–05–034					
University of Maryland, Baltimore	U45MC00174	1–Jul-05—30–Jun-10	$400,000	31–Jan-11	$233,333
The Regents of the University of California.	U45MC00175	1–Jul-05—30–Jun-10	$400,000	31–Jan-11	$233,333
Public Policy Analysis and Education Center for Early Childhood Health Cooperative Agreement, HRSA–05–115					
Columbia University	U05MC05056	1–Jul-05—30–Jun-10	$350,000	31–Jan-11	$204,167
National Healthy Child Care America Cooperative Agreement Program, HRSA–05–058					
University of North Carolina at Chapel Hill.	U46MC00003	1–Oct-97—31–Mar-10	$350,000	31–Jan-11	$291,667
American Academy of Pediatrics	U46MC04436	1–Apr-05—31–Mar-10	$350,000	31–Jan-11	$291,667
University of Colorado Health Sciences Center.	U46MC09810	1–Apr-08—31–Mar-10	$375,000	31–Jan-11	$312,500
Sudden Infant Death Syndrome Cooperative Agreement Program, HRSA–05–100					
Association of SIDS and Infant Mortality Programs.	U48MC05548	1–Sep-05—31–Aug-10	$200,000	31–Jan-11	$83,333
The Sudden Infant Death Syndrome Alliance.	U48MC05549	1–Sep-05—31–Aug-10	$250,000	31–Jan-11	$104,167
National SIDS Infant Death Resource Center, HRSA–07–040					
Georgetown University	U48MC08717	1–Sep-07—31–Aug-10	$350,000	31–Jan-11	$145,833

FOR FURTHER INFORMATION CONTACT: David Heppel, Director, Division for Child, Adolescent and Family Health, Health Resources and Services Administration, Maternal and Child Health Bureau, 5600 Fishers Lane, Room 18A39, Rockville, MD 20857, 301.443.2250; *dheppel@hrsa.gov.*

Justification for the Exception to Competition

The reason for this exception is to allow sufficient time for the HRSA's Maternal and Child Health Bureau (MCHB) to align its fiscal resources and programmatic goals:

- With the developing Maternal and Child Health Strategic Plan and with HRSA and Departmental plans; and,
- With the Early Learning and Development Initiative of the Department of Health and Human Services and the Department of Education; and, to maintain during this transition period MCH programmatic support to the State and community MCH constituencies which currently are receiving technical assistance services from these MCHB grantees.

The activities listed in the previous paragraph will not be completed in time for the FY 2010 grant competition. The MCHB proposes, therefore, to extend into FY 2011 the project periods of those grants scheduled to conclude in FY 2010 in order to have a larger and more current grant competition in FY 2011 reflective of any and all programmatic changes resulting from the above referenced activities and actions. Delaying the competition into FY 2011 also allows the MCHB additional time to consult with and provide information to constituency groups about changes in program direction. Providing an extension with funds to these grantees through January 31, 2011, will ensure the provision of technical assistance to the affected MCH constituencies continues without disruption.

Dated: February 9, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–3886 Filed 2–25–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0090]

Draft Guidance for Industry on Adaptive Design Clinical Trials for Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Adaptive Design Clinical Trials for Drugs and Biologics." The draft guidance provides sponsors and the review staff in FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) with information regarding adaptive design clinical trials when used in drug development programs. The draft guidance gives advice on various topics, such as what aspects of adaptive design clinical trials (i.e., clinical, statistical, regulatory) call for special consideration, when to interact with FDA while planning and conducting adaptive design studies, what information to include in the adaptive design for FDA review, and issues to consider in the evaluation of a completed adaptive design study. The draft guidance is intended to assist sponsors in planning and conducting adaptive design clinical studies, and to facilitate an efficient FDA review.

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 written or electronic comments on the draft guidance by June 1, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Robert T. O'Neill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3554, Silver Spring, MD 20993–0002, 301–796–1700; or

Sue-Jane Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3554, Silver Spring, MD 20993–0002, 301–796–1700; or

Marc Walton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4524, Silver Spring, MD 20993–0002, 301–796–2600; or

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Adaptive Design Clinical Trials for Drugs and Biologics." This guidance provides information regarding adaptive design trials when used in drug development programs.

There is great interest in the possibility that clinical trials can be designed with "adaptive" features (i.e., changes in design or analyses guided by examination of the accumulated data at an interim point in the trial) that can make the studies more efficient (e.g., shorter duration, fewer patients), more likely to demonstrate an effect of the drug if one exists, or more informative (e.g., by providing broader dose-response information). The draft guidance discusses clinical, statistical, and regulatory aspects of a wide range of adaptive design clinical studies that can be proposed as part of a drug development program, including both familiar and less familiar approaches. As more experience is obtained with the less familiar designs, sponsors can improve their understanding of circumstances where these designs are most useful or may pose risks to study integrity and interpretation. The draft guidance describes aspects of adaptive design trials that deserve special consideration and provides advice on the information that should be provided to FDA and how best to interact with FDA to facilitate an efficient review.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on adaptive design clinical trials for drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain