

The two-year data collection activity will include two phases: (1) A pilot test and (2) a psychometric field test. We will request information about the child care setting, its classrooms and families for recruitment into the study. Information will be collected through observations, focus groups, and questionnaires.

In the pilot and field tests, the new Q-CCIIT observation measure will include observing a small group activity structured with a common task and asking follow-up observation questions. Caregivers observed will also complete a background questionnaire. Focus

groups to obtain stakeholder input on caregiver-child interactions will be conducted separately with parents, caregivers, and training and technical assistance providers. Focus group participants will also complete a demographic questionnaire. Parents of children served by caregivers will complete a questionnaire on their child's competencies related to cognitive, language/communication, and social-emotional development. Parents will complete this questionnaire, which will also include family and child characteristics, once in

the pilot test and twice in the field test, at the start of the field test and 6 months later to assess growth.

The purpose of this data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110-134), which calls for periodic assessments of Head Start's quality and effectiveness.

Respondents: Child care setting representatives (directors or owners), caregivers (center-based and family child care settings), parents of children in those child care settings, and training and technical assistance providers.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
1. Child care setting recruitment form	190	1	0.5	95
2. Q-CCIIT measure-small group activity and follow-up	290	1	0.25	73
3. Caregiver background questionnaire	520	1	0.25	130
4. Focus group interview guide	20	1	1.90	38
5. Parent focus group demographic questionnaire	10	1	0.10	1
6. Caregiver focus group demographic questionnaire	5	1	0.10	1
7. Training and technical assistance provider focus group demographic questionnaire	5	1	0.10	1
8. Parent-report child competence questionnaire	880	2	0.75	1,320

Estimated Total Annual Burden Hours: 1,659.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202-395-6974, *Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

OPRE Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities; Notice of Correction of Room for Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID).

ACTION: Notice of correction of room for meeting.

DATES: Thursday, June 16, 2011, from 9:30 a.m. to 4 p.m. E.S.T.; and Friday, June 17, 2011, from 9 a.m. to 5 p.m. E.S.T. The meeting will be open to the public.

ADDRESSES: The meeting will be held in Conference Room 505-A of the Hubert H. Humphrey Building, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201. Individuals who would like to participate via conference call may do so by dialing 888-323-9869, *pass code:* PCPID. Individuals who will need accommodations for a disability in order to attend the meeting (e.g., sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should

notify Genevieve Swift, PCPID Executive Administrative Assistant, via e-mail at Edith.Swift@acf.hhs.gov, or via telephone at 202-619-0634, no later than June 10, 2011. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline. All meeting sites are barrier free.

Agenda: PCPID will meet to swear-in the new members of the Committee and set the agenda for the coming year.

Additional Information: For further information, please contact Laverdia Taylor Roach, Director, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447. *Telephone:* 202-619-0634. *Fax:* 202-205-9519. *E-mail:* LRoach@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human

Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: May 24, 2011.

Laverdia Taylor Roach,
Director, PCPID.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0362]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's Current Good Manufacturing Practice (CGMP) Regulations for Finished Pharmaceuticals.

DATES: Submit either electronic or written comments on the collection of information by August 1, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 301-796-7392,
Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—21 CFR Parts 210 and 211 (OMB Control Number 0910-0139)—Extension

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMPs to ensure that such drug meets the requirements of the FD&C Act as to safety, and has the

identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

FDA has the authority under section 701(a) of the FD&C Act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the FD&C Act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 CFR part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least 1 year after the expiration date of the batch and, for certain over the counter (OTC) drugs, 3 years after distribution of the batch (§ 211.180(a)). Records for all components, drug product containers, closures, and labeling are required to be maintained for at least 1 year after the expiration date and 3 years for certain OTC products (§ 211.180(b)).

All part 211 records must be readily available for authorized inspections during the retention period (§ 211.180(c)), and such records may be retained either as original records or as true copies (§ 211.180(d)). In addition, 21 CFR 11.2(a) provides that "for records required to be maintained but not submitted to the Agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met." To the extent this electronic option is used, the burden of maintaining paper records should be substantially reduced, as should any review of such records.

In order to facilitate improvements and corrective actions, records must be maintained so that data can be used for evaluating, at least annually, the quality