www.acf.hhs.gov/programs/ofs/forms.htm) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. Final programmatic and financial reports are due 90 days after the close of the project period.

Program Progress Reports: Quarterly.

Financial Reports: Quarterly.

VII. Agency Contacts

Program Office Contact: Willa Siegel, Administration on Children, Youth and Families, Head Start Bureau, 330 C Street, SW., Washington, DC 20447; Phone: 202–205–4011; E-mail: *WSiegel@acf.hhs.gov*.

Grants Management Office Contact: Delores Dickerson, Grants Officer, Administration on Children and Families, 330 C Street, SW., Room 2218, Washington, DC 20447; Phone: 202–260–7622; E-mail: *dedickenson@acf.hhs.gov*.

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005, applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov*. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html*.

Please reference Section IV.3 for details about acknowledgement of received applications.

Dated: July 18, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05–14558 Filed 7–22–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities: Notice of Meeting

AGENCY: President's Committee for People With Intellectual Disabilities (PCPID), HHS.

ACTION: Notice of meeting.

DATES: Thursday, September 15, 2005, from 9 a.m. to 5 p.m. and Friday, September 16, 2005, from 8:30 a.m. to 11:30 a.m. The full committee meeting of the President's Committee for People with Intellectual Disabilities will be open to the public.

ADDRESSES: The meeting will be held at the Aerospace Center Office Building, Aerospace Auditorium, 6th Floor East, 901 D Street, SW., Washington, DC 20447. Individuals with disabilities who need accommodations in order to attend and participate in the meeting (*i.e.*, interpreting services, assistive listening devices, materials in alternative format) should notify Sally Atwater at (202) 619–0634 no later than August 31, 2005. Efforts will be made to meet special requests received after that date, but availability of special needs accommodations to respond to these requests cannot be guaranteed. All meeting sites are barrier free.

Agenda: The Committee plans to discuss matters of major concern for people with intellectual disabilities: Comprehensive Health Care and Long Term Care, Dental Care, Housing and Aging of Caregivers, Emergency Preparedness and Direct Support Professional Challenges.

FOR FURTHER INFORMATION CONTACT: Sally Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, Aerospace Center Office Building, Suite 701, 901 D Street, SW., Washington, DC 20447, Telephone (202) 619–0634, Fax (202) 205–9519, e-mail *satwater@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: July 14, 2005.

Sally Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

[FR Doc. 05–14617 Filed 7–22–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0100]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 August 24, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

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 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, current good manufacturing practices (CGMPs) to ensure that such drug meets the requirements of the 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 act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the 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 ''[f]or 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 standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures (§ 211.180(e)). Written procedures for these evaluations are to be established and include provisions for a review of a representative number of batches and, where applicable, records associated with the batch; provisions for a review of complaints, recalls, returned or salvaged drug products; and investigations conducted under § 211.192 for each drug product.

The specific recordkeeping requirements provided in table 1 of this document are as follows:

- Section 211.34—Consultants advising on the manufacture, processing, packing, or holding of drug products must have sufficient education, training, and experience to advise on the subject for which they are retained. Records must be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.
- Section 211.67(c)—Records must be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§ 211.180 and 211.182.
- Section 211.68—Appropriate controls must be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.
- Section 211.68(a)—Records must be maintained of calibration checks, inspections, and computer or related system programs for automatic, mechanical, and electronic equipment.
- Section 211.68(b)—All appropriate controls must be exercised over all computers or related systems and control data systems to assure that changes in master production and controls records or other records are instituted only by authorized persons.
- Section 211.72—Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use must not release fibers into such products.
- Section 211.80(d)—Each container or grouping of containers for components or drug product containers or closures must be identified with a distinctive code for each lot in each shipment received. This code must be used in recording the disposition of each lot. Each lot must be appropriately identified as to its status.
- Section 211.100(b)—Written production and process control procedures must be followed in the execution of the various production and process control functions and must be documented at the time of performance. Any deviation from the written procedures must be recorded and justified.
- Section 211.105(b)—Major equipment must be identified by a distinctive identification number or code that must be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.
- Section 211.122(c) —Records must be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, or testing.
- Section 211.130(e)—Inspection of packaging and labeling facilities must be made immediately before use to assure that all drug products have been removed from previous operations. Inspection must also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection must be documented in the batch production records.
- Section 211.132(c)—Certain retail packages of OTC drug products must bear a statement that is prominently placed so consumers are alerted to the specific tamper-evident feature of the package. The labeling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-evident feature chosen is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement.
- Section 211.132(d)—A request for an exemption from packaging and labeling requirements by a manufacturer or packer is required to be submitted in the form of a citizen petition under 21 CFR 10.30.
- Section 211.137—Requirements regarding product expiration dating and compliance with 21 CFR 201.17 are set forth.
- Section 211.160(a)—The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, must be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. These requirements must be followed and documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or

other laboratory control mechanisms must be recorded and justified.

• Section 211.165(e)—The accuracy, sensitivity, specificity, and reproducibility of test methods employed by a firm must be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

• Section 211.166(c)—Homeopathic drug product requirements are set forth.

• Section 211.173—Animals used in testing components, in-process materials, or drug products for compliance with established specifications must be maintained and controlled in a manner that assures their suitability for their intended use. They must be identified, and adequate records must be maintained showing the history of their use.

• Section 211.180(e)—Written records required by part 211 must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures must be established and followed for such evaluations and must include provisions for a representative number of batches, whether approved or unapproved or rejected, and a review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

• Section 211.180(f)—Procedures must be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under § 211.198, § 211.204, or § 211.208, any recalls, reports of inspectional observations issued, or any regulatory actions relating to good manufacturing practices brought by FDA.

• Section 211.182—Specifies requirements for equipment cleaning records and the use log.

• Section 211.184—Specifies requirements for component, drug product container, closure, and labeling records.

• Section 211.186—Specifies master production and control records requirements.

• Section 211.188—Specifies batch production and control records requirements.

• Section 211.192—Specifies the information that must be maintained on the investigation of discrepancies found in the review of all drug product production and control records by the quality control staff.

• Section 211.194—Explains and describes laboratory records that must be retained.

• Section 211.196—Specifies the information that must be included in records on the distribution of the drug.

• Section 211.198—Specifies and describes the handling of all complaint files received by the applicant.

• Section 211.204—Specifies that records be maintained of returned and salvaged drug products and describes the procedures involved.

• Written procedures, referred to here as standard operating procedures (SOPs), are required for many part 211 records. The current SOP requirements were initially provided in a final rule published in the **Federal Register** of September 29, 1978 (43 FR 45014), and are now an integral and familiar part of the drug manufacturing process. The major information collection impact of SOPs results from their creation. Thereafter, SOPs need to be periodically updated. A combined estimate is provided in table 1 of this document. The 25 SOP provisions under part 211 in the combined maintenance estimate include:

• Section 211.22(d)—Responsibilities and procedures of the quality control unit;

• Section 211.56(b)—Sanitation procedures;

• Section 211.56(c)—Use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents;

• Section 211.67(b)—Cleaning and maintenance of equipment;

• Section 211.68(a)—Proper performance of automatic, mechanical, and electronic equipment;

• Section 211.80(a)—Receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers or closures;

• Section 211.94(d)—Standards or specifications, methods of testing, and methods of cleaning, sterilizing, and processing to remove pyrogenic properties for drug product containers and closures;

• Section 211.100(a)—Production and process control;

• Section 211.110(a)—Sampling and testing of in-process materials and drug products;

• Section 211.113(a)—Prevention of objectionable microorganisms in drug products not required to be sterile;

• Section 211.113(b)—Prevention of microbiological contamination of drug products purporting to be sterile, including validation of any sterilization process;

• Section 211.115(a)—System for reprocessing batches that do not conform to standards or specifications, to insure that reprocessed batches conform with all established standards, specifications, and characteristics;

• Section 211.122(a)—Receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials;

• Section 211.125(f)—Control procedures for the issuance of labeling;

• Section 211.130—Packaging and label operations, prevention of mixup and cross contamination, identification and handling of filed drug product containers that are set aside and held in unlabeled condition, and identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch;

• Section 211.142—Warehousing;

• Section 211.150—Distribution of drug products;

• Section 211.160—Laboratory controls;

• Section 211.165(c)—Testing and release for distribution;

• Section 211.166(a)—Stability testing;

• Section 211.167—Special testing requirements;

• Section 211.180(f)—Notification of responsible officials of investigations, recalls, reports of inspectional observations, and any regulatory actions relating to good manufacturing practice;

• Section 211.198(a)—Written and oral complaint procedures, including quality control unit review of any complaint involving specifications failures, and serious and unexpected adverse drug experiences;

• Section 211.204—Holding, testing, and reprocessing of returned drug products; and

• Section 211.208—Drug product salvaging.

Although most of the CGMP provisions covered in this document were created many years ago, there will be some existing firms expanding into new manufacturing areas and startup firms that will need to create SOPs. As provided in table 1 of this document, FDA is assuming that approximately 100 firms will have to create up to 25 SOPs for a total of 2,500 records, and the agency estimates that it will take 20 hours per recordkeeper to create 25 new SOPs, for a total of 50,000 hours.

The burden estimates for the recordkeeping requirements in table 1 of this document are based on the following factors: (1) FDA's institutional experience regarding creation and review of such procedures and similar recordkeeping requirements; and (2) data provided to FDA to prepare an economic analysis of the potential economic impact of the May 3, 1996,

proposed rule entitled ''Current Good Manufacturing Practice: Proposed Amendment of Certain Requirements for Finished Pharmaceuticals'' (61 FR 20104). Annual SOP maintenance is estimated to involve 1 hour annually per SOP, totaling 25 hours annually per recordkeeper.

The May 3, 1996, proposed rule revising part 211 CGMP requirements would require additional SOPs. Cost estimates for those additional SOPs were included in the proposed rule, but are not included here. Any comments on those estimates will be evaluated in any final rule based on that proposal.

In the **Federal Register** of March 28, 2005 (70 FR 15628), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
SOP Maintenance (See list of 25 SOPs in the **SUPPLEMENTARY INFORMATION** section of this document)	4,184	1	4,184	25	104,600
New startup SOPs	100	25	2,500	20	50,000
211.34	4,184	.25	1,046	.5	523
211.67(c)	4,184	50	209,200	.25	52,300
211.68	4,184	2	8,368	1	8,368
211.68(a)	4,184	10	41,840	.5	20,920
211.68(b)	4,184	5	20,920	.25	5,230
211.72	4,184	.25	1,046	1	1,046
211.80(d)	4,184	.25	1,046	.1	105
211.100(b)	4,184	3	12,552	2	25,104
211.105(b)	4,184	.25	1,046	.25	262
211.122(c)	4,184	50	209,200	.25	52,300
211.130(e)	4,184	50	209,200	.25	52,300
211.132(c)	1,698	20	33,960	.5	16,980
211.132(d)	1,698	.2	340	.5	170
211.137	4,184	5	20,920	.5	10,460
211.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	.5	4,184
211.173	1,077	1	1,077	.25	269
211.180(e)	4,184	.2	837	.25	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	.25	2,092
211.184	4,184	3	12,552	.5	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368

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

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
211.194	4,184	25	104,600	.5	52,300
211.196	4,184	25	104,600	.25	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	.5	20,920
Total					848,625

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

Dated: July 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14698 Filed 7–21–05; 11:48 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2005–0053]

Homeland Security Advisory Council

AGENCY: Office of the Secretary, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will hold a teleconference for the purposes of receiving a report and recommendations from a HSAC Task Force, and holding member deliberations. The HSAC will receive a final report from the HSAC Private Sector Information Sharing Task Force, Chaired by Mayor Patrick McCrory, Mayor of Charlotte, North Carolina. The Task Force will report on the topic of information sharing with the Private Sector. Following the Task Force report, the HSAC will hold deliberations and discussions among HSAC members.

DATES: This meeting will be held via teleconference on Wednesday, August 10, 2005, and will begin at 3:05 p.m. e.d.t.

ADDRESSES: If you desire to submit comments, they must be submitted by August 5, 2005. Comments must be identified by DHS–2005–0053 and may be submitted by *one* of the following methods:

- EPA Federal Partner EDOCKET Web Site: *http://www.epa.gov/feddocket*. Follow instructions for submitting comments on the Web site.
- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- E-mail: *HSAC@dhs.gov*. Include docket number in the subject line of the message.
- Fax: (202) 772–9718.
- Mail: Katie Knapp, Homeland Security Advisory Council, Department of Homeland Security, Washington, DC 20528.

Docket: For access to the docket to read background documents or comments received, go to *http://www.epa.gov/feddocket*. You may also access the Federal eRulemaking Portal at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information concerning the meeting, please contact Mike Miron or Katie Knapp of the HSAC Executive Staff Member via email at *HSAC@dhs.gov*, or via phone at (202) 692–4283.

SUPPLEMENTARY INFORMATION: *Public Attendance:* Members of the public may register to dial in and listen to this teleconference by contacting the Department officials listed above no later than 5 p.m., e.d.t., on Friday, August 5, 2005, via e-mail at *HSAC@dhs.gov*, or via phone at (202) 692–4283. Upon registration, instructions for the dial in will be provided. Persons with hearing disabilities who desire to obtain a transcript of the teleconference must request that the Department produce and provide a verbatim transcript based upon special needs due to a physical impairment at the time of registration. Absent any such request, the Department may not produce a verbatim transcript of the meeting.

Dated: July 19, 2005.

Kathryn Knapp,

Special Assistant, Homeland Security Advisory Council, U.S. Department of Homeland Security.

[FR Doc. 05–14603 Filed 7–20–05; 3:00 pm]

BILLING CODE 4410–10–P

DEPARTMENT OF THE INTERIOR

Central Utah Project Completion Act

AGENCY: Office of the Assistant Secretary—Water and Science, Interior.

ACTION: Notice of Availability of a Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for the execution of a lease of power privilege contract and the construction, operation, and maintenance of a non-federal hydroelectric generation facility on Jordanelle Dam, Wasatch County, Utah, pursuant to the lease.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended; Public Law 102–575, Central Utah Project Completion Act (CUPCA), as amended; a July 2, 1999, **Federal Register** notice (FR Doc. 99–16852); and a March 19, 2004, **Federal Register** notice (FR Doc. 04–6175); the Department of the Interior is making available a Final EA and FONSI for the execution of a lease of power privilege contract and the construction, operation, and maintenance of a non-federal hydroelectric generation facility on Jordanelle Dam, Bonneville Unit, Central Utah Project and associated power transmission lines and facilities. Through a competitive selection process the joint application of the Central Utah Water Conservancy District (District) and Heber Light and Power (HL&P) was selected as the potential lessee to develop hydropower at Jordanelle Dam. Construction and generation of power will be accomplished by the non-federal partnership of the District and HL&P through a lease of power privilege with the United States. A lease contract will be executed among the District, HL&P, and the Department, which defines the development, operation, and maintenance of a hydroelectric generation facility at Jordanelle Dam, consistent with the purposes and operations of the Bonneville Unit.