

and Units of Local Government, 42 U.S.C. 15421). Each State or Unit of Local Government must prepare and submit an annual report at the end of every fiscal year. The report addresses the activities conducted with the funds provided during the year. The information collected from the annual

report will be aggregated into an annual profile of how States have utilized the funds and establish best practices for election officials. It will also provide an overview of the State election goals and accomplishments and permit the Administration on Developmental

Disabilities to track voting progress to monitor grant activities.

**Respondents**

Secretaries of State, Directors, State Election Boards, State Chief Election officials.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Help America Vote Act (HAVA) Voting Access Annual Report .....	55	1	24	1,320
Help America Vote Act (HAVA) Voting Access Application .....	55	1	50	2,750.

*Estimated Total Annual Burden Hours: 4,070.*

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@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:* 202-395-7285. *E-mail:* [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV).

*Attn:* Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2011-15115 Filed 6-17-11; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Reunification Procedures for Unaccompanied Alien Children. *OMB No.:* 0970-0278.

**Description**

Following the passage of the 2002 Homeland Security Act (Pub. L. 107-

296), the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is charged with the care and placement of unaccompanied alien children in Federal custody, and implementing a policy for the release of these children, when appropriate, upon the request of suitable sponsors while awaiting immigration proceedings. In order for ORR to make determinations regarding the release of these children, the potential sponsors must meet certain conditions pursuant to section 462 of the Homeland Security Act and the Flores v. Reno Settlement Agreement No. CV85 4544-RJK (C.D. Cal. 1997). The proposed information collection requests information to be utilized by ORR for determining the suitability of a sponsor/respondent for the release of a minor from ORR custody. The proposed instruments are the Sponsors Agreement to Conditions of Release, Verification of Release, Family Reunification Packet, and the Authorization for Release of Information.

*Respondents:* Sponsors requesting release of unaccompanied alien.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Verification of Release (UAC) .....	4,595	1	0.25	1,148.75
Authorization for Release of Information (Sponsor) .....	4,595	1	0.25	1,148.75
Family Reunification Packet (Sponsor) .....	4,595	1	1	4,595
Sponsors Agreement to Conditions of Release (Sponsor) .....	4,595	1	0.25	1,148.75
Verification of Release (Case Worker) .....	4,595	1	0.25	1,148.75
Authorization for Release of Information (Case Worker) .....	4,595	1	0.25	.....
Family Reunification Packet (Case Worker) .....	4,595	1	1	4,595
Sponsors Agreement to conditions of Release (Case Worker) .....	4,595	1	0.25	1,148.75

*Estimated Total Annual Burden Hours: 16,082.50.*

**Additional Information**

Copies of the proposed collection may be obtained by writing to the

Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be

identified by the title of the information collection. *e-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@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: 202-395-7285, E-mail: [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov), Attn: Desk Officer for the Administration for Children and Families.

Dated: March 29, 2011.

**Robert Sargis,**

Reports Clearance Officer.

[FR Doc. 2011-15189 Filed 6-17-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA-2011-N-0447]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice**

**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 proposed collection of information resulting from the guidance to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP).

**DATES:** Submit either electronic or written comments on the collection of information by August 19, 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, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto: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 comment 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.

**Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice—(OMB Control Number 0910-0563)—Extension**

The guidance is intended to provide information to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to CGMP. Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements or during FDA's assessment of corrective actions undertaken as a result of such inspections. The guidance provides procedures that encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs (ORA) and center levels and for requesting review by the dispute resolution (DR) panel.

When a scientific or technical issue arises during an FDA inspection, the manufacturer should initially attempt to reach agreement on the issue informally with the investigator. Certain scientific or technical issues may be too complex or time consuming to resolve during the inspection. If resolution of a scientific or technical issue is not accomplished through informal mechanisms prior to the issuance of the FDA Form 483, the manufacturer can formally request DR and can use the formal two-tiered DR process described in the guidance.

Tier one of the formal DR process involves scientific or technical issues raised by a manufacturer to the ORA and center levels. If a manufacturer disagrees with the tier one decision, tier two of the formal DR process would then be available for appealing that decision to the DR panel.

The written request for formal DR to the appropriate ORA unit should be made within 30 days of the completion of an inspection and should include all supporting documentation and arguments for review, as described in this document. The written request for formal DR to the DR panel should be made within 60 days of receipt of the tier one decision and should include all supporting documentation and arguments, as described in the following paragraphs.

All requests for formal DR should be in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be