

regulations/practice/, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfpa.gov](mailto:Paperwork@hcfpa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 21, 2004.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 04-24077 Filed 10-27-04; 8:45 am]

**BILLING CODE 4120-03-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Computerized Support Enforcement Systems.

*OMB No.:* 0980-0271.

*Description:* The information being collected is mandated by section 454(16) of the Social Security Act (the Act), which provides for the establishment and operation by the state agency, in accordance with an initial and annually updated Advance Planning Document (APD) approved under section 452(d) of the Act, of a statewide system meeting the requirements of section 454A of the Act. In addition, 454A(e)(1) requires that states create a State Case Registry (SCR) within their statewide automated child support systems to include information on IV-D cases and non-IV-D orders established or modified in the state on or after October 1, 1998. Section 454A(e)(5) of the Act requires states to regularly update their cases in the SCR.

The data being collected for the ADP are a combination of narratives, budgets and schedules, which are used to provide funding approvals on an annual basis and to monitor and oversee system development. Child support has separate regulations under 45 CFR 307.15 related to submittal penalties for non-compliance with the statutory deadline of October 1, 2000. This information collection reflects the fact that 50 states and territories are now certified under the Personal

Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) leaving only four states that are not yet PRWORA systems certified, including one state that has not submitted an implementation APD for compliance with PRWORA automation. States and territories that opted to keep their Annual Planning Documents for child support systems are covered under a separate information collection, OMB No. 0992-0005, for 45 CFR part 95 subpart F.

The data being collected for the State Case Registry is used to transmit mandatory data elements to the Federal Case Registry (FCR) where it is used for matching against other data bases for the purposes of location of individuals, assets, employment and other child support related activities.

*Respondents:* The respondents are 54 state and territorial child support agencies.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
307.15 (APD) .....	1	1	240	240
307.15 (APD Update) .....	4	1	60	240
307.11(e)(1)(ii) Collection of non-IV-D data for SCR states .....	54	25,200	.046	62,597
307.11(e)(1)(ii) Collection of non-IV-D data for SCR courts .....	3,045	447	.029	39,472
307.11(e)(3)(v) Collection of child data for IV-D cases for SCR courts .....	3,045	213	.083	53,833
307.11(f)(1) Case data transmitted from SCR to FCR new cases and case updates .....	54	52	2.82	7,918

*Estimated Total Annual Burden Hours:* 164,300.

*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: [grjohnson@acf.hhs.gov](mailto:grjohnson@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, Attn: Desk Officer for ACF, E-mail address: [Katherine\\_T\\_Astrich@omb.eop.gov](mailto:Katherine_T_Astrich@omb.eop.gov).

Dated: October 20, 2004.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 04-24073 Filed 10-27-04; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0456]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mixups at Health Care Facilities; Survey**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing

that a collection of information entitled "Requirements for Collection of Data Relating to the Prevention of Medical Gas Mixups at Health Care Facilities; Survey" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of June 24, 2004 (69 FR 35379), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0548. The approval expires on March 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 22, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-24113 Filed 10-27-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Advisory Committee for Reproductive Health Drugs; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Advisory Committee for Reproductive Health Drugs.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on December 2, 2004, from 8 a.m. to 5:30 p.m.

*Location:* Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Teresa Watkins, Center for Drug Evaluation and Research

(HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [watkinst@cder.fda.gov](mailto:watkinst@cder.fda.gov) or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512537. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss new drug application (NDA) 21-769, Testosterone Transdermal System (proposed tradename, Intrinsa) by Procter and Gamble, indicated for the treatment of hypoactive sexual desire disorder in surgically menopausal women receiving concomitant estrogen therapy. Background materials for this meeting when available will be posted on the Internet 1 business day before the meeting at: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 17, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 17, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Teresa Watkins at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 21, 2004.

**Sheila Dearybury Walcoff,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-24068 Filed 10-27-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2001D-0584]

#### "Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Human Immunodeficiency Virus Type 1 and Hepatitis C Virus;" Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated October 2004. The guidance provides recommendations to all establishments that manufacture Whole Blood and blood components (including Source Plasma and Source Leukocytes) on the implementation of licensed nucleic acid tests (NAT) to identify human immunodeficiency virus type 1 (HIV-1) ribonucleic acid (RNA), and hepatitis C virus (HCV) RNA in donations of Whole Blood and blood components to reduce the risk of transmission of these agents; and the reporting to FDA of such implementation. The guidance announced in this notice finalizes the draft guidances entitled "Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated December 2001 and "Use of Nucleic Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV," dated March 2002.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug