

Mailstop F-59, 1600 Clifton Road NE., Atlanta, Georgia 30333, email: [viequesreport@cdc.gov](mailto:viequesreport@cdc.gov).

**SUPPLEMENTARY INFORMATION:** This report's principal focus is to review updated environmental data on Vieques air, water, soil, seafood, and locally grown foods. In addition, this report evaluates human biomonitoring and health outcome data. ATSDR is providing a public comment period for this draft report as a means to best serve public health and the residents of Vieques, Puerto Rico. The Draft Vieques Report is available in English and Spanish at [www.regulations.gov](http://www.regulations.gov) in the docket identified by Docket ID No. CDC-2011-0014 and [www.atsdr.cdc.gov/sites/vieques/](http://www.atsdr.cdc.gov/sites/vieques/).

Dated: December 13, 2011.

**Thomas Sinks,**

Deputy Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. 2011-32371 Filed 12-16-11; 8:45 am]

**BILLING CODE 4163-70-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*

*Title:* Plan for Foster Care and Adoption Assistance—Title IV–E.

*OMB No.:* 0980-0141.

*Description:* A title IV–E plan is required by section 471, part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care, adoption assistance and guardianship assistance under the Act. Section 479B of the Act provides for an Indian tribe, tribal organization or tribal consortium (Tribe) to operate a title IV–E program in the same manner as a State with minimal exceptions. The Tribe must have an approved title IV–E Plan. The title IV–E plan provides assurances the

programs will be administered in conformity with the specific requirements stipulated in title IV–E. The plan must include all applicable State or Tribal statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV–E agency may use the pre-print format prepared by the Children's Bureau of the Administration for Children and Families or a different format, on the condition that the format used includes all of the title IV–E plan requirements of the law.

*Respondents:* Title IV–E agencies administering or supervising the administration of the title IV–E programs.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E Plan .....	17	1	16	272

*Estimated Total Annual Burden Hours: 272.*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

Reports Clearance Officer.

[FR Doc. 2011-32410 Filed 12-16-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)**

*Title:* State Court Improvement Program.

*OMB No.:* New Collection.

*Description:* The Court Improvement Program (CIP) is composed of three

grants, the basic, data, and training grants, governed by two separate Program Instructions (PIs). The training and data grants are governed by the "new grant" PI and the basic grant is governed by the "basic grant" PI. Current PIs require separate applications and program assessment reports for each grant. Every State applies for at least two of the grants annually and most States apply for all three. As many of the application requirements are the same for all three grants, this results in duplicative work and high degrees of repetition for State courts applying for more than one CIP grant.

The purpose of this Program Instruction is to streamline and simplify the application and reporting processes by consolidating the PIs into one single PI and requiring one single, consolidated application (App) package and program assessment report (PAR) per State court annually. These revisions will satisfy statutory programmatic requirements and reduce both the number of required responses and associated total burden hours for State courts.

This new PI also describes programmatic and fiscal provisions and

reporting requirements for the grants, specifies the application submittal and approval procedures for the grants for fiscal years 2012 through 2015, and

identifies technical resources for use by State courts during the course of the grants. The agency uses the information received to ensure compliance with the

statute and provide training and technical assistance to the grantees.

*Respondents:* Highest State Courts of Appeal.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application .....	52	1	92	4784
Program Assessment Report .....	52	1	86	4472

*Estimated Total Annual Burden Hours:* 9256.

*Additional Information:* ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by December 20, 2011. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690-7275.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503; FAX: (202) 395-7285; email: [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

**Robert Sargis,**  
Reports Clearance Officer.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0230]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Examination of Online Direct-to-Consumer Prescription Drug Promotion

**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 January 18, 2012.

**ADDRESSES:** 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: FDA Desk Officer, FAX: (202) 395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title, Examination of Online Direct-to-Consumer Prescription Drug Promotion. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-7651, [juanmanuel.vilela@fda.hhs.gov](mailto:juanmanuel.vilela@fda.hhs.gov).

**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.

*Examination of Online Direct-to-Consumer Prescription Drug Promotion—(OMB Control Number 0910—New)*

#### I. Background

Pharmaceutical products are launched and marketed in a number of new modalities and venues that did not exist a short time ago. Increasingly, prescription products are promoted to consumers online in such formats as banners, Web sites, and videos. The interactive nature of the Internet allows for features not possible with traditional media (i.e., print, radio, and television), such as scrolling information, popup windows, linking to additional information, and embedded videos. FDA regulations require that prescription drug advertisements include a “fair balance” of information about the benefits and risks of

advertised products, both in terms of the content and presentation of the information (21 CFR 202.1(e)(5)(ii)). All prescription drug promotion that makes claims about a product must, therefore, also include risk information in a “balanced” manner. Currently, there are a number of questions surrounding how to achieve “fair balance” in online direct-to-consumer (DTC) promotion.

A few studies have examined how well online DTC Web sites communicate benefit and risk information. Although content analyses demonstrate that most Web sites include information on side effects and contraindications (Ref. 1), risk information is often presented less prominently and in fewer locations on the Web site (Refs. 2, 3, and 4). Content analyses also suggest that risk information on DTC prescription drug Web sites is often incomplete (Ref. 5) and written at very high literacy levels (Ref. 6).

One study examined how users interact with prescription drug Web sites (Ref. 7). This study found that the placement of risk and benefit information on a Web site is an important factor in whether it achieves “fair balance.” Specifically, participants’ ability to find and accurately recall risk information was enhanced when risk and benefit information were presented separately and when risk information was presented on a higher order page (i.e., on a second-level page clearly linked from the homepage, or on the homepage).

This project is designed to test different ways of presenting prescription drug risk and benefit information on branded drug Web sites. This research is relevant to current policy questions and debate and will complement qualitative research we plan to conduct on issues surrounding social media. The series of studies described in this document will provide data that, along with other input and considerations, will inform the development of future guidance.