Proposed Project

Voluntary Product Satisfaction and Usability Assessment—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Executive Order 12862 directs Federal agencies that provide services directly to the public to survey customers to determine the kind and quality of services they need and their level of satisfaction with existing services.

CDC releases a number of new products each year to its customers, a diverse group that includes health care providers, researchers, public health practitioners, policy makers, and the general public. The term product is broadly defined to include publications, Web pages, podcasts, e-cards, CD–ROMs, and videos. At present, there is no mechanism for evaluating whether these products are meeting customer needs.

CDC is requesting a 3-year generic clearance in order to better evaluate its products. Obtaining feedback from customers on a regular, on-going basis will help ensure that customers find CDC products to be useful. This type of evaluation will allow CDC to maximize the impact of its products which will ultimately benefit the public's health.

The target audience will be limited to customers who request and receive CDC products. Customer participation in the evaluation is completely voluntary. Names of customers will not be collected. The only personal information collected will relate to professional discipline, job duties, and experience working with public health topics. No sensitive data (*e.g.,* age, race, or gender) will be collected. The evaluation data will be collected using a combination of methodologies including:

1. *Response cards via mail:* Each product that is sent out will include a one-page response card along with a self-addressed and stamped envelope. Customers can then voluntarily choose whether to return the response card.

2. *E-mail announcements:* Products are released to customers via an e-mail announcement that includes a link to the electronic version of the product plus a link to a Web-based evaluation. Customers can then voluntarily choose whether to complete the evaluation.

3. *Web-based assessments:* Products are available on-line in an electronic format. Each product Web page will include a link to a Web-based evaluation. Customers can then voluntarily choose whether to complete the evaluation.

The information being collected will not impose a cost burden on the respondents beyond that associated with their time to provide the required data.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Evaluation method	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Customers	Response cards	50,000	1	10/60	8,333
	E-mail Assessments	60,000	1	10/60	10,000
	Web-Based Assessments	432,000	1	10/60	72,000
Total					90,333

Dated: July 22, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services; Notice To Award a Single Source Program Expansion Supplement Under the American Recovery and Reinvestment Act (ARRA) to Technical Assistance by Community Action Program Legal Services, Inc.

AGENCY: Office of Community Services, ACF, HHS.

ACTION: Notice to award a Single Source Program Expansion Supplement under the American Recovery and Reinvestment Act (ARRA) to Technical Assistance by Community Action Program Legal Services, Inc.

CFDA#: 93.710.

Legislative Authority: The legislative authority for this award is provided in the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5). Additional legislative authority and requirements are provided in Section 674(b)(2)(B) of the CSBG Act, as amended, by the Community Opportunity Accountability, and Training and Educational Services (Coats Human Services Reauthorization Act of 1998) (Pub. L. 105–285).

Amount of Supplemental Award: $96,952.

Project Period: September 30, 2006 through September 30, 2009.

SUMMARY: The Office of Community Services (OCS) announces the awarding of a $96,952 single source program expansion supplement to the Community Action Legal Services, Inc. (CAPLAW), located in Boston, MA, to support training and technical assistance on legal issues faced by Community Action Agencies (CAAs) related to the American Recovery and Reinvestment Act of 2009 (ARRA). The project activities are designed to support and strengthen the ability of the CAA network to comply with, and carry out, Community Services Block Grant (CSBG) activities funded by ARRA. The training projects and resources developed under the award will include analysis and explanation of the practical impact of ARRA for States and CSBG-eligible entities so that they can work more effectively to reach the ARRA goals and document how they have in fact reached those goals and used the ARRA funds. The project's overall approach is based on the following five key elements: (1) Technical assistance and issue-specific consultation; (2) Publications, including online postings on the CAPLAW Web site, e-Bulletins, and a print newsletter, which is also available on CAPLAW's Web site; (3) Online toolkit; (4) Presentations at CAA conferences, including CAPLAW's 2009 national training conference, and CAPLAW audio conferences.

The training and technical assistance CAPLAW will provide is particularly critical at this time due to the large temporary increase in funding of CSBG awards to eligible entities and the need for both rapid implementation of these programs and adherence to high

standards of accountability and tracking of awards and results.

Contact for Further Information: Danielle Williams, U.S. Department of Health and Human Services, Office of Community Services, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20047.

Telephone: (202) 205–4717. *E-mail: Danielle.Williams@acf.hhs.gov.*

Dated: July 15, 2009.

Yolanda J. Butler,

Acting Director, Office of Community Services.

[FR Doc. E9–17890 Filed 7–27–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0379]

Guidance for Industry: Nucleic Acid Testing To Reduce the Possible Risk of Human Parvovirus B19 Transmission by Plasma-Derived Products; 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: Nucleic Acid Testing (NAT) to Reduce the Possible Risk of Human Parvovirus B19 Transmission by Plasma-Derived Products,'' dated July 2009. The guidance document provides to manufacturers of plasma-derived products recommendations for performing parvovirus B19 NAT as an in-process test for Source Plasma and recovered plasma to identify and help to prevent the use of plasma units containing high levels of parvovirus B19. The guidance also recommends how to report to FDA implementation of parvovirus B19 NAT. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 2008.

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, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Nucleic Acid Testing (NAT) to Reduce the Possible Risk of Human Parvovirus B19 Transmission by Plasma-Derived Products,'' dated July 2009. Parvovirus B19 is a small, non-enveloped single stranded DNA virus. Virus clearance studies, using non-human parvoviruses as models for parvovirus B19, have indicated that this virus is highly resistant to all commonly used inactivation methods, including heat and solvent/detergent (S/D) treatment, and is also difficult to remove by filtration because of its small size. More recent studies have demonstrated that human parvovirus B19 may be more readily cleared than certain model animal parvoviruses. The parvovirus B19 can be transmitted by blood components and certain plasma derivatives and may cause morbidity to susceptible recipients such as pregnant women, persons with underlying hemolytic disorders, and immune compromised individuals. The disease transmission from transfusion of blood components is rare. However, extremely high levels of parvovirus B19 in plasma of acutely infected but asymptomatic donors may present a greater risk in plasma derivatives due to pooling of large numbers of units of these products in the manufacturing process.

The guidance provides recommendations for performing parvovirus B19 NAT as an in-process test for Source Plasma and recovered plasma used in the further manufacturing of plasma-derived products to identify and help to prevent the use of plasma units containing high levels of parvovirus B19. The guidance also recommends how to report to FDA implementation of parvovirus B19 NAT.

In the **Federal Register** of July 30, 2008 (73 FR 44272), FDA announced the availability of the draft guidance of the same title, dated July 2008. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to minor editorial changes made to improve clarity, changes to the draft guidance include the addition of 4 references to reflect recent studies that show B19 may be less resistant to inactivation than animal-derived parvoviruses that have been used as models; and removal of the recommendation on the acceptable limit for B19 DNA titer in individual plasma units. The guidance announced in this notice finalizes the draft guidance dated July 2008.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12(a)(2) and 601.12(c)(5), have been approved under OMB No. 0910–0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://*