

discrimination on the basis of age, disability, sex, race, color, national origin, or religion.

(11) Funds made available under the FVPSA will be used to supplement and not supplant other Federal, State and local public funds expended to provide services and activities that promote the objectives of the FVPSA (section 10406(c)(6)).

(12) Receipt of supportive services under the FVPSA will be voluntary. No condition will be applied for the receipt of emergency shelter (section 10408(d)(2)).

(13) The Tribe has a law or procedure to bar an abuser from a shared household or a household of the abused person, which may include eviction laws or procedures (section 10407(a)(2)(H)).

\_\_\_\_\_  
Tribally Designated Official

\_\_\_\_\_  
Tribe or Tribal Organization

## Appendix B

### LGBTQ (also known as “Two-Spirited”) Accessibility Policy

As the Authorized Organizational Representative (AOR) signing this application on behalf of

[Insert full, formal name of applicant organization]

I hereby attest and certify that:

The needs of lesbian, gay, bisexual, transgender, and questioning (also known as “Two-Spirited”) program participants are taken into consideration in applicant’s program design. Applicant considered how its program will be inclusive of and non-stigmatizing toward such participants. If not already in place, awardee and, if applicable, sub-awardees must establish and publicize policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin. The submission of an application for this funding opportunity constitutes an assurance that applicants have or will put such policies in place within 12 months of the award. Awardees should ensure that all staff members are trained to prevent and respond to harassment or bullying in all forms during the award period. Programs should be prepared to monitor claims, address them seriously, and document their corrective action(s) so all participants are assured that programs are safe, inclusive, and non-stigmatizing by design and in operation. In addition, any sub-awardees or subcontractors:

- Have in place or will put into place within 12 months of the award policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin;
- Will enforce these policies;
- Will ensure that all staff will be trained during the award period on how to prevent and respond to harassment or bullying in all forms, and;
- Have or will have within 12 months of the award, a plan to monitor claims, address them seriously, and document their corrective action(s).

Insert Date of Signature:

Print Name and Title of the AOR:

Signature of AOR:

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0377]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission

**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 collection of health documents that were created during the period of June 23, 2009, through December 31, 2009.

**DATES:** Submit either electronic or written comments on the collection of information by June 10, 2013.

**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:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [daniel.gittleston@fda.hhs.gov](mailto:daniel.gittleston@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 comments 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.

#### Tobacco Health Document Submission—(OMB Control Number 0910-0654)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding, among other things, a new chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Tobacco Control Act created many new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the FD&C Act by adding, among other things, section 904(a)(4) (21 U.S.C. 387d(a)(4)).

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, “that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives” (herein referred to as “tobacco health documents”).

FDA announced the availability of a guidance on this collection in the **Federal Register** of April 20, 2010 (75 FR 20606), and requested tobacco health documents that were created during the period from June 23, 2009, through December 31, 2009. The guidance stated that information required under section 904(a)(4) must be submitted to FDA beginning December 22, 2009. Further, FDA stated it would publish a revised guidance specifying the timing of subsequent reporting. FDA is in the process of revising the April 2010 guidance but will continue collecting documents created during the specified period for any manufacturers, importers, or their agents who still have documents to submit.

FDA has been collecting the information submitted pursuant to section 904(a)(4) through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. In both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification: Submitter type, company name, address, country, company headquarters Dun and Bradstreet number, and company headquarters Facility Establishment Identifier number;
- Submitter point of contact: Contact name, title, position title, email, telephone, and fax; and

- Submission format and contents (as applicable):
  - Electronic documents: Media type, media quantity, size of submission, quantity of documents, file type, and file software;
  - Paper documents: Quantity of documents, quantity of volumes, and quantity of boxes; and
  - Whether or not a submission is being provided.
- Confirmation statement (with identification and signature of submitter including name, company name, address, position title, email, telephone, and fax); and
- Document categorization (as applicable): Relationship of the document or set of documents to the following:
  - Health, behavioral, toxicological, or physiological effects;
  - Specific current or future tobacco product(s);
  - Class of current or future tobacco product(s);
  - Specific ingredient(s), constituent(s), component(s), or additive(s);
  - Class of ingredient(s), constituent(s), component(s), or additive(s).
- Document readability and accessibility: Keywords; glossary or explanation of any abbreviations, jargon, or internal (e.g., code) names; special instructions for loading or compiling submission; and
- Document metadata: Date document was created, document author(s),

document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, and Bates number ranges for documents attached to a submitted email.

In addition to the electronic and paper forms, the guidance that FDA issued in April 2010 (75 FR 20606) was intended to assist persons making tobacco health document submissions. For further assistance, FDA is providing a technical guide, embedded hints, and a Web tutorial on the electronic portal.

The estimated 50 hours per response burden is based on the average burden estimate among all 4 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance. The number of documents received each year since the original collection period has fallen to less than 5 percent of the number received in the original collection period. FDA expects this is because documents created within the specified period have already been submitted. Also, the number of respondents who still have documents to submit has decreased. Therefore, FDA estimates the biannual burden of the continuation of this collection to be at most, 5 percent of the original burden.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743 .....	4	2	8	50	400

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 4, 2013.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
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**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request**

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will

submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office at (301) 443-1984.

*Information Collection Request Title:* Corps Community Day Event Form (OMB No. 0915-xxxx)—[NEW]

*Abstract:* Corps Community Day was created in 2011 and celebrates the