

factor information collected through donor interviews of blood donor with the resulting data from disease marker testing and blood components collected by participating organizations into a research database. Following successful initiation of the risk factor interviews, the TTIMS network is poised to be expanded to include additional blood centers and/or re-focused on other safety threats as warranted. In this way, the TTIMS program will maintain standardized, statistically and scientifically robust processes for applying hemovigilance information across blood collection organizations.

The specific objectives are to:

- Determine current behavioral risk factors associated with all HIV infections, incident HBV, and incident HCV infections in blood donors (including parenteral and sexual risks) across the participating blood collection organizations using a case-control study design.
- Determine infectious disease marker prevalence and incidence for

HIV, HBV, and HCV overall and by demographic characteristics of donors in the majority of blood donations collected in the country. This will be accomplished by forming epidemiological databases consisting of harmonized operational data from ARC, BSI, NYBC, and OneBlood.

- Analyze integrated risk factor and infectious marker testing data concurrently because when taken together these may suggest that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

The respondents will be persons who donated blood in the United States and these participants will be defined as cases and controls. The estimated number of respondents is based on an overall expected participation in the risk factor survey. We estimate a case to control ratio of 1:2 (200 to 400) with a 50 percent case enrollment.

In the **Federal Register** of September 30, 2016 (81 FR 67358), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received a few comments from the public. FDA concurs with one comment that providing more information to the blood center and FDA may aid in prevention of transmission of infectious disease and is critical to the safety of the blood supply. Four comments received were not responsive to the comment request on the four specified aspects of the collection of information. None of the responses specifically commented on any of the proposed questions, nor did they request that FDA make any other changes to the Donor Risk Assessment Questionnaire. Furthermore, the responses did not provide any data or explanation that would support a change regarding the information collection requirements.

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

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

Questionnaire/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cases and controls <sup>2</sup> .....	600	1	600	0.75 (45 minutes) .....	450

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

<sup>2</sup> Cases consist of virus-positive donations, and controls represent uninfected donors.

Dated: December 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-D-0508]

**Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishment; Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” This guidance is intended to assist persons making tobacco product establishment

registration and product listing submissions to FDA.

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

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2009-D-0508 for “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product

Establishments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for

information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a revised guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)).

We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). Persons who owned or operated domestic manufacturing establishments engaged in the manufacture of newly deemed products prior to August 8, 2016, and continued to own or operate such establishment(s) on or after August 8, 2016, are required to register and submit product listing under section 905 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387e) by December 31, 2016. However, FDA is announcing that it does not intend to enforce these requirements with respect to newly deemed products provided the registration and product listing submissions are received by FDA on or before June 30, 2017. Although this guidance document is immediately effective, it remains subject to comment in accordance with FDA’s GGP regulation.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) added section 905 to the FD&C Act, establishing requirements for tobacco product establishment registration and product listing. Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA’s tobacco product authorities in chapter IX of the FD&C Act, including section 905, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a(b)) grants FDA authority to deem those products subject to chapter IX of the FD&C Act.

Pursuant to that authority, on April 25, 2014, FDA issued a proposed rule seeking to deem all other products that meet the statutory definition of tobacco product, set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) (except for accessories of those products) (79 FR 23142). After review and consideration of comments on the proposed rule, FDA published the final rule on May 10, 2016 (81 FR 28974) (“the deeming rule”) and it became effective on August 8, 2016. As a result, owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products subject to the deeming rule are now required to comply with chapter IX of the FD&C Act, including the establishment registration and product listing requirements in section 905. The guidance addresses tobacco products that were immediately covered by FDA’s tobacco product authorities under chapter IX of the FD&C Act and newly deemed tobacco products.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements 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 section 905 of the FD&C Act have been approved under OMB control number 0910–0650.

##### **III. Electronic Access**

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: December 7, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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