

finalized, will supersede the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

**DATES:** Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 2, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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

**FOR FURTHER INFORMATION CONTACT:** Lori Jo Churchyard, 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 revised, second draft document entitled "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" dated January 2011. The draft guidance document provides blood establishments with recommendations for pre-storage leukocyte reduction of Whole Blood and blood components intended for transfusion, including recommendations for validation and quality control monitoring of the leukocyte reduction process. The draft guidance provides information to assist licensed blood establishments for submitting biologics license application supplements to include leukocytes reduced components. This second draft guidance document incorporates revisions after reviewing comments on the January 2001 draft, and in consideration of

additional public discussions held at the June and December 2001 meetings of the Blood Products Advisory Committee and the July 2005 public workshop entitled "Update on Leukocyte Reduction of Blood and Blood Components." This draft guidance replaces the draft guidance of the same title dated January 2001 (January 31, 2001, 66 FR 8410). The draft guidance, when finalized, will supersede the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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 part 607 have been approved under OMB control number 0910-0052; the collections of information in 21 CFR 606.100(b), 606.100(c), and 606.121 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR 211.192 and 211.198 have been approved under OMB control number 0910-0139; and the collections of information in 21 CFR 601.12 and 610.60 have been approved under OMB control number 0910-0338.

**III. Comments**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen 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 draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: January 25, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0281]

**Guidance for Industry and Food and Drug Administration Staff: "Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act"; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled "Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act." This guidance provides written guidance to industry and FDA staff on certain provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

**DATES:** Submit either electronic or written comments on this guidance at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your requests or include a fax number to which the guidance document may be sent. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Carol Drew, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 301-796-3505.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of June 10, 2010 (75 FR 32952), FDA announced the availability of a draft guidance entitled "Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act." The Agency considered received comments as it finalized this guidance. The guidance document discusses the meaning of the term "harmful and potentially harmful constituent" in the context of implementing the listing requirements of section 904(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387d(e)).

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111-310) into law. The Tobacco Control Act amended the FD&C Act by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 904(e) of the FD&C Act, as added by the Tobacco Control Act, requires FDA to establish, and periodically revise as appropriate, "a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand." The guidance discusses the meaning of the term "harmful and potentially harmful constituent" in the context of implementing the listing requirements of section 904(e).

**II. Significance of Guidance**

This guidance is being issued as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the meaning of the term "harmful and potentially harmful constituents" in the context of section 904(e) of the FD&C Act. 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 requirements of the applicable statutes and regulations.

**III. Comments**

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen 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 document at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/GuidanceCompliance/RegulatoryInformation/default.htm>.

Dated: January 25, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Resources and Services Administration****Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the 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.

**Proposed Project: Ryan White HIV/AIDS Program Part F Dental Services Report (OMB No. 0915-0151)— [Extension]**

The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program under Part F of the Ryan White HIV/AIDS Program, offer funding to accredited dental education programs to support the provision of oral health services for HIV-positive individuals. Institutions eligible for these Ryan White HIV/AIDS Programs are accredited schools of dentistry, post-doctoral dental education programs, and dental hygiene programs.

The DRP Application is the Dental Services Report that schools and programs use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV, or to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. 300ff-111(b)). The Dental Services Report collects data in four different areas: Program information, patient demographics and services, funding, and training. It also requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

The primary purpose of collecting this information annually is to verify eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of Community-Based Dental Partnership Program grant recipients. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive HIV/AIDS program-supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected in the Dental Services Report is critical for HRSA, state and local grantees, and individual providers, to help assess the status of existing HIV-related health service delivery systems.

The annual estimate of burden is as follows: