

drug application (ANDA) review process more efficient.

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 24, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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:** Radhika Rajagopalan, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., MPN2, Rm. 243, HFD-640, Rockville, MD 20855, 240-276-8546.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a draft guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products." Because of increases in numbers of ANDAs and their complexity, the FDA is considering standardizing stability testing policies by adopting recommendations in the following stability related ICH guidances: (1) "Q1A (R2) Stability Testing of New Drug Substances and Products," November 2003; (2) "Q1B Photostability Testing of New Drug Substances and Products," November 1996; (3) "Q1C Stability Testing for New Dosage Forms," November 1996; (4) "Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products," January 2003; and (5) "Q1E Evaluation of Stability Data," June 2004. FDA is also considering adopting the ICH outlined definitions, glossaries, references, and attachments.

Although the ICH stability guidances were developed for new drug applications to ensure the stability of new drug substances and products, FDA

believes the recommendations provided in the ICH guidances on stability testing are appropriate for ANDAs as well. This guidance contains FDA's recommendation that ANDAs submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and the drug master files that support ANDAs, follow the stability recommendations provided in the ICH stability guidances.

This guidance also replaces stability study storage condition recommendations made in an August 18, 1995, letter that the Center for Drug Evaluation and Research's (CDER's) Office of Generic Drugs (OGD) sent to all ANDA applicants, which is available on CDER's Web site: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064995.htm>. The letter stated that OGD would accept ANDAs with the ICH recommended long term room temperature conditions for stability studies, 25 ± 2°C, 60 ± 5 percent RH.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on stability testing of drug substances and products for ANDAs. 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.

##### **II. 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. 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, and will be posted to the docket at <http://www.regulations.gov>.

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

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 18, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-23543 Filed 9-24-12; 8:45 am]

**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2001-D-0254 (Formerly Docket No. 2001D-0037)]

#### **Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion; 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: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" dated September 2012. The 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 guidance announced in this notice finalizes the draft guidance of the same title dated January 2011 and supersedes the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

**DATES:** Submit either electronic or written 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 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 document entitled "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" dated September 2012. The 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 guidance also provides information to assist licensed blood establishments for submitting biologics license application supplements to include leukocytes reduced components.

In the **Federal Register** of January 31, 2011 (76 FR 5386), FDA announced the availability of the draft guidance of the same title dated January 2011. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes the following: Removing the recommendation for use of a mixing device during collection, modifying definitions, and clarifying performance qualification criteria. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated January 2011 and supersedes the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

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

The 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 and Form FDA 2830 have been approved under OMB control number 0910-0052; the collections of

information in 21 CFR 606.100(b), 606.100(c), 606.121, and 606.122 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 and Form FDA 356h have been approved under OMB control number 0910-0338.

##### III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

##### IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 18, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-23542 Filed 9-24-12; 8:45 am]

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#### DEPARTMENT OF HOMELAND SECURITY

##### Federal Emergency Management Agency

[Docket ID FEMA-2012-0028]

##### Fee for Services To Support FEMA's Offsite Radiological Emergency Preparedness Program

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) is establishing a fiscal year (FY) 2014 hourly rate of \$57.41 for assessing and collecting fees from Nuclear Regulatory Commission (NRC) licensees for services provided by FEMA personnel for FEMA's Radiological Emergency Preparedness (REP) Program.

**DATES:** This hourly rate is effective for FY 2014 (October 1, 2013, to September 30, 2014).

##### FOR FURTHER INFORMATION CONTACT:

Andrew Mitchell, Director, Technological Hazards Division, Department of Homeland Security/FEMA, 1800 S. Bell Street—CC826, Mail Stop 3025, Arlington, VA 20598-3025; (202) 646-2618 (phone), or (email) [Andrew.Mitchell2@fema.dhs.gov](mailto:Andrew.Mitchell2@fema.dhs.gov).

**SUPPLEMENTARY INFORMATION:** As authorized by 42 U.S.C. 5196e, FEMA collects fees from NRC licensees of commercial nuclear power plants to offset the costs of its REP program. The fees that FEMA receives are deposited in the Treasury's REP Program Fund to offset the actual costs by FEMA for its REP Program. The methodology FEMA uses to assess and collect this fee is in FEMA's regulations at Title 44 Code of Federal Regulations (CFR) part 354. FEMA assesses user fees from licensees using a methodology that includes charges for REP Program services provided by both FEMA personnel and FEMA contractors. The fee for each site consists of two distinct components: (1) A site-specific, biennial exercise-related component, and (2) a flat fee component.

As required by regulation, FEMA annually revises the hourly rate used in 44 CFR 354.4(b) for site-specific, biennial exercise-related costs for FEMA personnel to reflect actual budget and cost of living factors. In FY 2014, FEMA will use an hourly rate of \$57.41 to calculate the site-specific, biennial exercise-related component of the user fee for services that FEMA personnel provide in 44 CFR 354.4(b). This hourly rate does not apply to: (1) Services that FEMA contractor personnel provide under the site-specific, exercise-related component of the user fee, or (2) services provided by FEMA personnel under the flat fee component of the user fee. FEMA will determine the cost for the site-specific, biennial exercise-related component for FEMA contractor personnel services in accordance with 44 CFR 354.4(c). FEMA will determine the flat fee component of the user fee in accordance with 44 CFR 354.4(d).

Dated: September 12, 2012.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2012-23596 Filed 9-24-12; 8:45 am]

**BILLING CODE 9110-21-P**