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In the **Federal Register** of January 31, 2011 (76 FR 5386), FDA announced the availability of the draft guidance of the same title dated January 2011. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized.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 The guidance announced in this notice finalizes the draft guidance dated January 2011 and supersedes the FDA memorandum issued on May 29, 1996, entitled ''Recommendations and Licensure Requirements for Leukocyte-Reduced Blood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.*

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]

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