

Proposed Rules

This section of the **FEDERAL REGISTER** contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM13-5-000]

Version 5 Critical Infrastructure Protection Reliability Standards

AGENCY: Federal Energy Regulatory Commission, Energy.

ACTION: Notice of Proposed Rulemaking; correction.

SUMMARY: This document contains corrections to the proposed rule (RM13-5-000) which was published in the **Federal Register** of Wednesday, April 24, 2013 (78 FR 24107). The regulations proposed to approve certain reliability standards proposed by the North American Electric Reliability Corporation.

DATES: Effective on June 24, 2013.

FOR FURTHER INFORMATION CONTACT: Kevin Ryan (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (202) 502-6840.

SUPPLEMENTARY INFORMATION:

Errata Notice

On April 18, 2013, the Commission issued an “Notice of Proposed Rulemaking” in the above-captioned proceeding, *Version 5 Critical Infrastructure Protection Reliability Standards*, 143 FERC ¶ 61,055 (2013).

This errata notice serves to correct P 119 and the table in P 124. Specifically, in P 119, the reference to “CIP version 4” in the fifth line is changed to “CIP version 5.” In addition, in the table in P 124, the “Total Burden Hours in Year 2” estimate is changed to “1,162,788 hrs” and the “Total Burden Hours in Year 3” estimate is changed to “757,948 hrs.”

In FR Doc. 2013-09643 appearing on page 24107 in the **Federal Register** of

Wednesday, April 24, 2013, the same corrections are made:

1. On page 24121, the reference to “CIP version 4” in the fifth line is changed to “CIP version 5.”
2. On page 24122, the “Total Burden Hours in Year 2” estimate is changed to “1,162,788 hrs” and the “Total Burden Hours in Year 3” estimate is changed to “757,948 hrs.”

Dated: May 3, 2013.

Kimberly D. Bose,

Secretary

[FR Doc. 2013-10956 Filed 5-8-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2013-N-0402]

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for public comments.

The Food and Drug Administration (FDA or the Agency) is announcing a public meeting that will provide an overview of the current status of the regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested stakeholders—as it fulfills its statutory requirement under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public meeting into account in developing the fiscal year (FY) 2014 Regulatory Science Plan.

DATES: Date and Time: The public meeting will be held on June 21, 2013, from 9 a.m. to 5 p.m. Submit electronic or written requests to make oral presentations and comments by June 7, 2013. Electronic or written comments will be accepted after the public meeting until July 19, 2013, but

Federal Register

Vol. 78, No. 90

Thursday, May 9, 2013

submission of comments before the meeting is strongly encouraged.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Comments: Submit electronic comments 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.

Transcripts: Transcripts of the public meeting will be available for review at the Division of Dockets Management and on the Internet at: <http://www.regulations.gov> approximately 30 days after the public meeting. A live Webcast of this public meeting will be available at: <https://collaboration.fda.gov/regscipart15/>.

Contact Persons: Thushi Amini, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., MPN-2, Rm. N-142, Rockville, MD 20855, 240-276-8433, email: Thushi.Amini@fda.hhs.gov; or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 7519 Standish Pl., MPN-4, Rm. 3015A, Rockville, MD 20855, 240-276-9315, email: Robert.Lionberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and to reduce costs to industry. To support this goal, FDA agreed in the GDUFA commitment letter to the FY 2013 Regulatory Science Plan, and to consult