

Proposed Rules

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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]

BILLING CODE 6717–01–P

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

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

with industry and the public in order to create an annual list of regulatory science initiatives specific to research on generic drugs for each subsequent year covered by GDUFA. The FY 2013 Regulatory Science Plan consisted of the following research topics:

1. Bioequivalence of local acting, orally inhaled drug products
2. Bioequivalence of local acting topical dermatological drug products
3. Bioequivalence of local acting gastrointestinal drug products
4. Quality by design of generic drug products
5. Modeling and simulation
6. Pharmacokinetic studies and evaluation of anti-epileptic drugs
7. Excipient effects on permeability and absorption of Biopharmaceutics Classification System Class 3 drugs
8. Product- and patient-related factors affecting switchability of drug-device combinations
9. Postmarketing surveillance of generic drug usage patterns and adverse events
10. Evaluation of drug product physical attributes on patient acceptability
11. Postmarketing assessment of generic drugs and their brand-name counterparts
12. Physicochemical characterization of complex drug substances
13. Develop a risk-based understanding of potential adverse impacts to drug product quality resulting from changes in active pharmaceutical ingredients manufacturing and controls

II. Purpose and Scope of the Public Meeting

The purpose of the public meeting is to provide a forum for the public to provide recommendations to FDA related to regulatory science initiatives in generic drug research. FDA is requesting input from industry and other stakeholders as it develops the FY 2014 Regulatory Science Plan for generic drug research, with a focus on the following:

1. Identification of current regulatory science challenges that limit the availability of generic drug products
2. Regulatory science approaches to improve the preapproval evaluation of therapeutic equivalence of generic drug products
3. Postapproval regulatory science approaches to ensure the therapeutic equivalence of approved generic drug products
4. Prioritization of FY 2014 regulatory science research topics for generic drug products based on public health impact

5. Areas where additional draft guidance is needed to clarify FDA recommendations on complex generic drug product development

FDA will consider all comments made at this meeting or received through the docket (see section V, Request for Comments) as it develops its FY 2014 GDUFA Regulatory Science Plan. Additional information concerning GDUFA, including the text of the law and the letter in which the Agency describes its commitments may be found on the FDA Web site at <http://www.fda.gov/gdufa>.

III. Attendance, Registration, and Presentations

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend and/or present at the meeting, please register for the meeting and/or make a request for oral presentation by email to GDUFARegulatoryScience@fda.hhs.gov by June 7, 2013. The email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Those without email access may register by contacting Thushi Amini by June 7, 2013 (see *Contact Persons*).

If you need special accommodations because of a disability, please contact Thushi Amini or Robert Lionberger (see *Contact Persons*) at least 7 days before the meeting. For those unable to attend in person, FDA will provide a Webcast to the meeting. To join the meeting via the Webcast, please go to: <https://collaboration.fda.gov/regscipart15/>.

FDA will try to accommodate all persons who wish to make a presentation. These individuals should identify the section and the number of each question they wish to address (see section II) in their presentation to help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for presentations will depend on the number of individuals who wish to speak. Persons registered to make an oral presentation should check in before the meeting and are encouraged to arrive early to ensure the designated order of presentation times. An agenda for the meeting and other background material will be made available 5 days before the meeting at <http://www.fda.gov/Drugs/NewsEvents/ucm344710.htm>. Once FDA notifies registered presenters of their scheduled times, they should submit an electronic copy of their presentation to

GDUFARegulatoryScience@fda.hhs.gov on or before June 14, 2013.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C) (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VI). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see *Comments*). 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>.

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may also be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be made available in either hardcopy or on CD-ROM upon submission of a Freedom of Information

request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013-11007 Filed 5-8-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA-2013-D-0446]

Draft Guidance for Industry on Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Expanded Access to Investigational Drugs for Treatment Use—Qs & As.” This guidance is intended to provide information for industry, researchers, physicians, and patients about certain aspects of FDA’s implementation of its regulations on expanded access to investigational drugs for treatment use. FDA has received a number of questions about implementation of its expanded access regulations. Therefore, FDA is providing this draft guidance in a question and answer format, addressing the most frequently asked questions.

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 July 8, 2013.

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 or Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401

Rockville Pike, suite 200N, Rockville, MD 20852-1448. 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: *For the Center for Drug Evaluation and Research:* Colleen L. Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993-0002, 301-796-2270.

For the Center for Biologics Evaluation and Research: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Expanded Access to Investigational Drugs for Treatment Use—Qs & As.” FDA’s expanded access regulations (21 CFR part 312, subpart I) went into effect on October 13, 2009 (74 FR 40900).

These regulations contain the requirements for the use of investigational new drugs or approved drugs where availability is limited by a risk evaluation and mitigation strategy (REMS), when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition. Under these regulations, there are three categories of expanded access based on the size of the patient population to be treated: (1) Individual patient access, including for emergency use; (2) intermediate-size patient population access; and (3) larger population access under a treatment protocol or treatment investigational new drug application (IND). These regulations are intended to facilitate the availability of investigational new drugs, or approved drugs where availability is limited by a REMS, to patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and may benefit from investigational therapies.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance

entitled “Charging for Investigational Drugs Under an IND—Qs & As,” which is intended to provide information about FDA’s implementation of its regulation on charging for investigational drugs under an investigational new drug applications, including investigational drugs made available under expanded access programs.

One of FDA’s major goals in promulgating these expanded access regulations was to make expanded access a more transparent process by increasing awareness and knowledge of expanded access programs and the procedures for obtaining investigational drugs for treatment use. Since these expanded access regulations went into effect in 2009, FDA has received a number of questions concerning its implementation of the regulations. Consistent with the goal of making expanded access processes more transparent, FDA is providing this draft guidance to address frequently asked questions about how it is interpreting various provisions in the expanded access regulations, including questions about when it is appropriate to request access under each of the three access categories, the types and content of access submissions, IRB review of individual patient expanded access, and the onset and duration of access use.

Although FDA is inviting comment on the entire draft guidance (21 CFR 10.115(g)(1)(ii)(C)), FDA notes that it is particularly interested in receiving comments on question 10. Question 10 asks, “Is Institutional Review Board (IRB) review and approval required for individual patient expanded access?” In the draft guidance, FDA explains that under current regulations for all expanded access uses, including individual patient access uses, investigators are required to ensure that IRB review and approval is obtained consistent with 21 CFR part 56 (21 CFR 312.305(c)(4)). 21 CFR part 56 requires, among other things, that an IRB review the expanded access use at a convened meeting at which a majority of the IRB members are present (“full IRB review”) (21 CFR 56.108(c)). However, FDA is aware of concerns that this requirement for full IRB review may deter individual patient access to investigational drugs for treatment use. FDA has encouraged use of central IRBs for review of expanded access uses to address these concerns. However, other options may be needed. Therefore, FDA is particularly interested in receiving comments on this issue, including to what extent the requirement for full IRB review of individual patient expanded access is a deterrent to patient access,