4160-01-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.

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 (Public Law 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.

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