4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2014-N-1168]

Generic Drug User Fee Amendments of 2012; Public Hearing on Policy Development; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to solicit public comment on certain topics related to implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA), and the GDUFA Commitment Letter that accompanies the legislation. The public hearing also will provide an opportunity for public input on future policy priorities. FDA is seeking participation in the public hearing and written comments from all interested parties, including, but not limited to, regulated industry, consumers, patients, caregivers, health care professionals, and patient groups.

DATES: The public hearing will be held on September 17, 2014, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation. Submit electronic or written requests to make oral presentations at the hearing by September 3, 2014. Electronic or written comments will be accepted after the hearing until October 13, 2014.

ADDRESSES: The public hearing will be held at the College Park Marriott Hotel and Conference Center, 3501 University Blvd., East, Hyattsville, MD 20783.

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 all comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Shaniece Bowens, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1611, 240-402-7923, email: shaniece.bowens@fda.hhs.gov; or Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1674, 240-402-7946, email: connie.wisner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The Hatch-Waxman Amendments created section 505(j) of the FD&C Act (21 U.S.C. 355(j)). Section 505(j) of the FD&C Act established the abbreviated new drug application (ANDA) approval pathway, which allows lower-priced generic versions of previously approved innovator drugs to be approved and marketed.

On July 9, 2012, GDUFA was signed into law by the President to help speed the delivery of safe and effective generic drugs to the public and to reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter that

accompanies the legislation.[1] To support these obligations, FDA is developing numerous guidance documents. Thus far, FDA has developed the following draft guidances for industry:[2]

- ANDA Submissions--Content and Format of ANDAs
- ANDA Submissions--Refuse to Receive for Lack of Proper Justification of Impurity Limits
- ANDA Submissions--Amendments and Easily Correctable Deficiencies Under GDUFA
- ANDA Submissions--Prior Approval Supplements Under GDUFA
- Controlled Correspondence Related to Generic Drug Development

II. Purpose and Scope of the Public Hearing

A. GDUFA Implementation: Draft Guidance Documents

The purpose of this public hearing is to (1) solicit public comment on the five draft guidance documents described in section I that FDA has issued to facilitate implementation of GDUFA and (2) recommend future policy priorities, including recommendations for additional guidance topics to facilitate GDUFA implementation. We are soliciting comments from interested members of the public, including industry, consumers, patient groups, caregivers, and health care professionals, on the following topics related to GDUFA implementation guidances:

1. Are there comments on the five draft guidances described in section I?

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[1] See Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA Commitment Letter) for fiscal years 2013 through 2017, available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf).

[2] The draft guidance documents referenced in this document are available on the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

2. Are there GDUFA implementation issues related to the five draft guidances described in section I that have not been addressed?

3. What other GDUFA implementation topics need the development of guidance?

4. Are there any topics or issues related to generic drug development other than those related to GDUFA implementation that need the development of guidance?

B. GDUFA Implementation Related to Generic Drug Exclusivity

Another purpose of this hearing is also to solicit feedback on issues that may arise in FDA's consideration of 180-day exclusivity provided for in section 505(j)(5)(B)(iv) of the FD&C Act.

Timing of ANDA approval is directly affected by an applicant's eligibility for 180-day exclusivity, and thus FDA's consideration of any issues related to 180-day exclusivity is a component of approval actions. FDA decisions regarding 180-day exclusivity are fact-specific, and the facts that have the potential to determine eligibility for exclusivity may shift up to the time when an ANDA that is eligible for 180-day exclusivity, or another ANDA referencing the same listed drug, is ready for approval.

With the enactment of GDUFA, FDA will take actions on pending applications consistent with the timeframes agreed upon in the GDUFA Commitment Letter. In this hearing, we are seeking input on possible processes FDA might introduce under GDUFA for making determinations on 180-day exclusivity, as described in the following questions. When submitting input on the questions provided in this document, we encourage commenters to consider FDA's statutory and regulatory authorities, including any restrictions on FDA's

authority to disclose certain information related to unapproved ANDAs. We are seeking comment on the following topics:

1. Should FDA's consideration of eligibility for 180-day exclusivity for a specific drug product be a public process, including consideration of whether a first applicant has forfeited its eligibility for exclusivity under section 505(j)(5)(D) of the FD&C Act? If a public process is advisable, would it be so in all instances, or is there a subset of circumstances in which the process should be public? Also, what administrative mechanisms would best facilitate such a process?

2. Legal challenges to FDA's decisions on 180-day exclusivity often must be resolved on an expedited basis which can be inconvenient for the parties and the court. What legal or regulatory mechanisms, if any, are available to better facilitate FDA's determination of and orderly resolution of sponsors' challenges to 180-day exclusivity determinations?

3. Are there other topics related to 180-day exclusivity on which you would like to comment?

4. Are there topics related to 180-day exclusivity that would benefit from FDA guidance?

C. GDUFA Implementation and Potential First Generics

The GDUFA Commitment Letter also provides that certain ANDAs may be identified at the date of submission for expedited review, including ANDAs for "first generic products for which there are no blocking patents or exclusivities on the reference listed drug."[3] Subsequent to GDUFA's enactment, FDA has received numerous individual stakeholder comments on what should qualify as a first generic ANDA for the purposes of expedited review. These comments reflect a range of options, for example, from a broad definition that would prioritize review of all

[3] GDUFA Commitment Letter, at 15.

ANDAs for each strength of a Reference Listed Drug submitted for which there is not already an approved ANDA at the time of submission, to a more narrow definition under which only ANDAs that contain a paragraph IV certification and qualify as a "first applicant" under section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act would be designated as a first generic eligible for expedited review. In addition, several stakeholders have indicated that depending on the criteria FDA applies, first generic status could or should change over time based on other external factors, for example, withdrawal or rescission of approval of another applicant's ANDA, or shifts in the patent or exclusivity landscape (for example, an unsuccessful patent challenge).

In order to meet the goals in the GDUFA Commitment letter with respect to expedited ANDA review, we will be prioritizing ANDA review consistent with the recently issued Manual of Policies and Procedures (MAPP) 5240.3 Rev. 1: Prioritization of the Review of Original ANDAs, Amendments, and Supplements, and MAPP 5200.4: Criteria and Procedures for Managing the Review of Original ANDAs, Amendments and Supplements.[4] In order to meet the goals of the GDUFA Commitment Letter related to first generics in particular, in a manner that best effectuates the intent of the negotiators, we are seeking comment on the following questions:

1. What specific criteria should FDA apply to identify an ANDA as a first generic eligible for expedited ANDA review?

2. Are there other topics related to first generics eligible for expedited review on which you would like to comment?

III. Attendance, Registration, and Presentations

[4] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/

Attendance is free and on a first-come, first-served basis. We recommend that you register early because seating is limited.

If you wish to attend the hearing and/or make an oral presentation at the hearing, please register and/or send a request for oral presentation by email to GenericDrugPolicy@fda.hhs.gov by September 3, 2014. 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 Shaniece Bowens or Connie Wisner by September 3, 2014 (see FOR FURTHER INFORMATION CONTACT).

Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation is scheduled to begin. 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, and make available an agenda at http://www.fda.gov/Drugs/NewsEvents/ucm265628.htm approximately 2 weeks before the public hearing. Once FDA notifies registered presenters of their scheduled times, presenters should submit an electronic copy of their presentation to GenericDrugPolicy@fda.hhs.gov by September 9, 2014. Persons registered to make an oral presentation should check in before the hearing and are encouraged to arrive early to ensure the designated order of presentation times.

If you need special accommodations because of a disability, please contact Shaniece Bowens or Connie Wisner (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the hearing.

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 Generic Drugs and other relevant Agency components. 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 (§ 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). 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 for more details.) To the extent that the conditions for the hearing as described in this document 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 ADDRESSES). 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.

To ensure consideration, submit comments by (see DATES). 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 be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hard copy or on CD-ROM, after 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: August 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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