

Book.<sup>1</sup> The language for enhanced capacity is included in section III of the proposed BsUFA II commitment letter.

#### *I. Enhancing Management of User Fee Resources*

FDA is committed to enhancing management of BsUFA resources and ensuring BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. In BsUFA II, FDA proposes to establish a resource capacity planning function to improve its ability to analyze current resource needs and project future resource needs, to modernize its time reporting approach, to conduct an evaluation of BsUFA program resource management, to publish a 5-year BsUFA financial plan with annual updates, and to convene an annual public meeting, beginning in FY 2019, to discuss the financial plan and progress towards the financial management enhancements. FDA also proposes to reduce the carryover balance to no greater than 21 weeks of the FY 2022 target revenue by the end of FY 2022. These enhancements are described in section IV of the proposed BsUFA II commitment letter.

#### *J. Enhancements to Fee Structure and Related Mechanisms for Increased Predictability, Stability, and Efficiency*

The current BsUFA fee structure references PDUFA fees each fiscal year and calculates biosimilar biological product development program (BPD) fees based on the PDUFA application fee. FDA and industry agreed that the BsUFA II fee structure and the fee setting process could be updated to enhance the predictability and stability of fee amounts and revenues in a manner to improve FDA's ability to engage in long-term financial planning. To address these issues, FDA proposes to discontinue the reduction of the biosimilar biological product application fee by the cumulative BPD fees paid by sponsors, to discontinue the establishment and supplement fees, to rename the product fee as the BsUFA Program fee, to modify the Program fee billing date to minimize the need for multiple billing cycles, and to add a limitation that a sponsor shall not be assessed more than five BsUFA Program fees for a fiscal year for products identified in each distinct approved biosimilar biological product application held by that sponsor.

<sup>1</sup> The "Purple Book" lists biological products, including any interchangeable biological products, licensed by FDA under the Public Health Service Act.

#### *K. Enhancements to User Fee Revenue Amounts and Adjustments*

FDA and industry agreed that the BsUFA II user fee revenue amounts and fee amounts should be independent of PDUFA and based on BsUFA program costs. FDA proposes to establish fees to generate a total of \$45 million in user fee revenue for FY 2018. However, FDA also proposes that it can adjust this amount when setting the user fee amounts published in the FY 2018 **Federal Register** notice to reflect an updated assessment of the BsUFA workload, with the limitation that this adjustment cannot increase user fee revenue by more than \$9 million (*i.e.* relative to the \$45 million specified for FY 2018 user fee revenue). To enhance the predictability of user fee amounts, FDA proposes that the amount for each BsUFA fee cannot increase more than 25 percent from the respective FY2018 fee amount until the capacity planning adjustment is effective and that FDA can otherwise modify the amount of the user fee revenue generated from each fee type each fiscal year. FDA proposes to adjust the annual user fee revenue amount for inflation, to develop a robust methodology for adjusting fees based on the capacity needs of the program, and to introduce an annual operating reserve adjustment to provide for adequate carryover resources.

#### **IV. Purpose and Scope of the Meeting**

If you wish to attend this meeting, visit <http://bsufapublicmeeting.eventbrite.com>. Please register by October 19, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

The meeting will include a presentation by FDA and a series of invited panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated

industry). We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

FDA will also hold an open public comment period at the meeting to give the public an opportunity to present their comments. Registration for open public comment will occur at the registration desk on the day of the meeting and workshop on a first-come, first-served basis.

*Transcripts:* As soon as a transcript is available, FDA will post it at <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm461774.htm>.

Dated: September 13, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2016-N-2673]

#### **Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act." This public meeting is intended to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to share information with FDA about the efforts underway to implement the Drug Supply Chain Security Act's (DSCSA's) product identification requirements, including the use of product identifiers to enhance tracing at the product level.

**DATES:** The public meeting will be held on October 14, 2016, from 9 a.m. to 4 p.m. To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is November 14, 2016.

**ADDRESSES:** The public meeting will be held at FDA's White Oak Campus,

10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), 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>.

You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2016-N-2673 for "Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain

Security Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4285, Silver Spring, MD 20993, 301-796-3130, FAX: 301-847-8722, email: [CDERODSIRPublicMeetings@fda.hhs.gov](mailto:CDERODSIRPublicMeetings@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

## **I. Background**

On November 27, 2013, the DSCSA (Title II, Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they are distributed within the United States. This system will enhance FDA's ability to protect U.S. consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful by improving the detection and removal of potentially dangerous drugs from the drug supply chain.

Section 582(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360eee-1), which was added by the DSCSA, directs FDA to hold at least five public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide opportunities for comment from stakeholders. In carrying out these public meetings, FDA is required to prioritize topics necessary to inform the guidances described in section 582(h)(3) and (h)(4) related to unit-level tracing and standards for the interoperable data exchanges, respectively, and to take all reasonable and practicable measures to ensure the protection of confidential commercial information and trade secrets. FDA is also required to address each of the eight topics enumerated in section 582(i)(2) in at least one of the five required public meetings.

FDA will hold a public meeting on October 14, 2016, to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to share information about current practices and industry efforts to implement the DSCSA's product identification requirements, including the use of product identifiers. The format of the meeting involves presentations from the public and followup questions from an FDA panel. FDA will not be inviting specific presenters; rather, with this notice, FDA is soliciting presentations from interested stakeholders.

## **II. Topics for This Public Meeting**

The main topic FDA is interested in discussing at the public meeting is the supply chain's progress toward implementing the DSCSA's product identification requirements, including best practices in each sector of the pharmaceutical distribution supply chain to conduct product tracing, verification, and product identification. This may include the processes needed to utilize the product identifiers to

enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary. (The product identifier is a standardized graphic that includes, in both human- and machine-readable forms, the National Drug Code, serial number, lot number, and expiration date of the product.) Under section 582(b)(2) and (e)(2) of the FD&C Act, manufacturers and repackagers must affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce, by November 2017 and November 2018, respectively.

Other topics of interest to FDA that may be presented at the public meeting include, but are not limited to:

- An assessment of the steps taken by supply chain members to build capacity for a unit-level system for electronic product tracing, including the impact on (1) the ability of the health care system to maintain patient access to medicines; (2) the scalability of such requirements, including as it relates to product lines; and (3) the capability of different sectors and subsectors, including both large and small businesses, to affix and utilize the product identifier; and
- information related to the secure, interoperable electronic data exchange among sectors within the pharmaceutical distribution supply chain.

FDA will post the agenda of the meeting at <http://www.fda.gov/Drugs/NewsEvents/ucm519587.htm>.

### III. Registration

Registration to attend is free and will be on a first-come, first-served basis. To register for the meeting either: (1) Email your registration information to [CDERODSIRPublicMeetings@fda.hhs.gov](mailto:CDERODSIRPublicMeetings@fda.hhs.gov), or (2) mail your registration information to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Registration information should include:

- “Registration for October 14, 2016, DSCSA meeting” in the subject line, and
- Registrant name, company or organization, address, phone number, and email address in the body of your email or mailing.

Registration requests should be received by October 6, 2016. Onsite registration on the day of the meeting, starting at 8 a.m., will be based on space availability. Seating will be limited; therefore, if registration meets the maximum capacity, FDA will post a notice closing meeting registration for the meeting on FDA’s Web site at: <http://www.fda.gov/Drugs/NewsEvents/ucm519587.htm>.

If you need special accommodations due to a disability, please contact Daniel Bellingham (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the public meeting.

### IV. Requests for Oral Presentations

Any person interested in presenting at the public meeting should include a request to present in a single email with a registration request (see section III. Registration). The request should specify the topic(s) that will be addressed in the presentation. FDA will do its best to accommodate requests for oral presentations. Individuals and organizations with common interests are encouraged to consolidate or coordinate their presentations and can submit a single request to present.

All requests to make oral presentations must be received by October 5, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled public comment session, FDA may conduct a lottery to determine the speakers for the public comment session. The contact person will notify interested persons regarding their request to speak by October 7, 2016. Presenters must email their presentation materials, if any, to [CDERODSIRPublicMeetings@fda.hhs.gov](mailto:CDERODSIRPublicMeetings@fda.hhs.gov) no later than October 12, 2016. This meeting is not intended to be a venue for circulation of product-specific promotional material, but rather an opportunity to gather information related to stakeholder progress towards implementing the product identification requirements of the DSCSA.

### V. Webcasting of the Public Meeting

Portions of this public meeting will be recorded and Webcast on the day of the meeting. Information for how to access the Webcast will be available at <http://www.fda.gov/Drugs/NewsEvents/ucm519587.htm> by October 14, 2016. The Webcast will be conducted in listening mode only.

Dated: September 13, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-2610]

#### **A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (such as academic researchers, regulated industries, consortia, and patient groups) on a list of biomarkers that were used as outcomes to develop FDA-approved new molecular entities (NMEs) and New Biological Therapeutics from October 2007 to December 2015. Comments received on this list will help FDA determine the utility of the list and may assist FDA in developing databases on biomarkers for drug development in the future.

**DATES:** Submit either electronic or written comments by November 18, 2016.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you