

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, 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 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

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-2610 for “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 Public Docket.” 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:

Marianne Noone, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993-0002, 301-796-2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to support more efficient drug development by providing scientific, technical, and regulatory advice to stakeholders (such as to pharmaceutical industries, academia, patient advocacy groups, and consortia). As part of this commitment, FDA is providing a list of biomarkers that were used as outcomes in the development of FDA-approved NMEs and New Biological Therapeutics in different disease areas from October 2007 to December 2015. This list is intended to provide examples of biomarkers that were accepted and used as endpoints in clinical trials for drug and biologic approvals from October 2007 to December 2015. This list, along with brief background information, is accessible at Biomarkers Used as Outcomes in Development of FDA-Approved Therapeutics (October 2007 to December 2015).

II. Establishment of a Public Docket and Request for Comments

FDA is soliciting suggestions and comments from stakeholders to determine the utility of the biomarker outcomes list and to identify any areas of improvement for disseminating information on biomarkers that have been used to support the approval of drugs or biologics. Specifically, FDA welcomes comments regarding the following two areas:

- Areas of improvement for communicating and disseminating information about biomarkers and their utility as drug development tools.

- The best approach for updating the biomarkers outcomes list, including any modifications of the list, in the future.

FDA will consider all comments submitted but will generally not respond directly to the person or organization submitting the comment.

Dated: September 14, 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-D-2569]

S9 Nonclinical Evaluation for Anticancer Pharmaceuticals—Questions and Answers; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled “S9 Nonclinical Evaluation for Anticancer Pharmaceuticals—Questions and Answers.” The draft questions and answers (Q&As) guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft Q&As guidance provides recommendations for nonclinical studies for the development of pharmaceuticals, including both small molecule and biotechnology-derived products, intended to treat patients with cancer. The Q&As are intended to provide additional clarity for topics discussed in the ICH guidance entitled “S9 Nonclinical Evaluation for Anticancer Pharmaceuticals” (S9 guidance).

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 November 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way: