process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received, and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on November 6, 2013 (78 FR 66745). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Amphotericin B.
	Atorvastatin calcium; Ezetimibe.
	Axitinib.
B	Brinzolamide.
	Buprenorphine.
	Buprenorphine hydrochloride.
	Buprenorphine hydrochloride; Naloxone hydrochloride.
C	Clobazam.
D	Desoximetasone (multiple reference listed drugs and dosage forms).
	Diazoxide.
E	Erythromycin.
	Estradiol.
F	Fentanyl citrate.
G	Guaifenesin.
H	Hydrochlorothiazide; Metoprolol succinate.
L	Levonorgestrel (multiple reference listed drugs).
	Linagliptin; Metformin hydrochloride.
M	Mesalamine.
P	Perampanel.
	Pindolol.
	Prednisolone acetate.
R	Rabeprazole sodium.
T	Teriflunomide.
	Tranylcypromine sulfate.
V	Verteporfin.

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Abiraterone acetate.
	Amlodipine besylate; Benazepril hydrochloride.
B	Brimonidine tartrate (multiple reference listed drugs).
D	Doxycycline hyclate.
	Dronabinol.
	Dutasteride; Tamsulosin hydrochloride.
I	Icosapent Ethyl.
L	Leuprolide acetate (multiple reference listed drugs and strengths).
M	Metoprolol succinate.
	Morphine sulfate.
	Mycophenolate mofetil (multiple reference listed drugs and dosage forms).
	Mycophenolic acid.
N	Naltrexone.
O	Octreotide acetate.
T	Trimethoprim.
	Triptorelin pamoate

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please go to *http://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessaary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and 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*.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07330 Filed 4–1–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0337]

Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format.'' This public workshop will provide a forum for discussing the development of these standards in the Drug Supply Chain Security Act of 2013. In particular, participants will be asked to provide information, current practices, research, and ideas on the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for each transfer of drug product in which a change of ownership occurs. This public workshop will also provide a forum to discuss the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey this information to the subsequent purchaser of a drug product and to facilitate the exchange of lot level data. As FDA continues to work on developing standards for interoperable exchange, the Agency is seeking public input to ensure that we consider information regarding all drug supply chain stakeholders.

DATES: The public workshop will be held on May 8 and 9, 2014, from 9 a.m. to 5 p.m.

ADDRESSES: The public workshop 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.*

FOR FURTHER INFORMATION CONTACT: Connie T. Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3130, FAX: 301–847–8722, email: *drugtrackandtrace@fda.hhs.gov*.

Comments: In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is June 9, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding the topics of the workshop to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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*.

Registration: To register for the workshop either: (1) Email your registration information to *drugtrackandtrace@fda.hhs.gov* or (2) mail your registration information to Connie T. Jung (see *Contact Person*). Registration information should include:

- ''Registration'' 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 April 24, 2014. Registration is free. Seats are limited. FDA may limit the numbers of participants from each organization based on space limitations. Registrants will receive confirmation upon acceptance for participation in the workshop. Onsite registration on the day of the meeting will be based on space availability on the day of the event starting at 8 a.m. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop on FDA's Web site at: *http://www.fda.gov/Drugs/NewsEvents/ucm388993.htm*.

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

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II, Pub. L. 113–54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system over the next 10 years to identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA, which adds section 582(a)(2)(A) to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), requires the Secretary to establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale drug distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders. The system that will be established under the DSCSA will enhance FDA's ability to help protect U.S. consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful by improving detection and removal of potentially dangerous drugs from the drug supply chain.

FDA has used a multilayered approach to improve the security of the drug supply chain to protect U.S. patients from unsafe, ineffective, and poor quality drugs. In addition to considering the standards developed under section 505D of the FD&C Act (21 U.S.C. 355e), the DSCSA directs FDA to establish initial standards for trading partners to utilize to achieve the interoperable exchange of transaction information, transaction history, and transaction statements. On February 20, 2014, FDA issued a **Federal Register** notice (79 FR 9745) that established a public docket (Docket No. FDA–2014–N–0200) for this topic. FDA is seeking additional stakeholder input based on the information received in that docket.

II. Purpose of the Workshop

This public workshop is intended to provide an opportunity for interested persons to share information, current practices, research, and ideas on the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a drug product and to facilitate the exchange of lot level data. In addition, FDA is interested in learning about practices, processes, and systems that supply chain stakeholders currently use to exchange information, such as product information, information related to the sale or change of ownership of prescription drugs, or communications about drugs in distribution. Discussions at this public workshop may also include current practices and suggestions for the exchange of information between supply chain stakeholders to provide, receive, and terminate notifications. Discussions may also include how trading partners should respond to requests for verification of suspect drug product, and respond to requests for information from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate drug product. Participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. By May 2, 2014, FDA will post the following information on our Web site under Standards Development for Interoperable Exchange of Tracing Information at *http://www.fda.gov/Drugs/NewsEvents/ucm388993.htm:*

- Workshop agenda;
- Workshop discussion topics.

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07335 Filed 4–1–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–E–0677 and FDA–2011–E–0678]

Determination of Regulatory Review Period for Purposes of Patent Extension; ONSIOR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ONSIOR and is publishing this notice of that determination as required by law. FDA has made the determination