quality efforts. This event will also focus on various topics of interest for those industry representatives who are responsible to insure compliance with FDA regulations.

DATES: The meeting will be held on April 15, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at Courtyard and Towne Place Suites by Marriott, DFW Airport North/Grapevine, 2200 Bass Pro Ct., Grapevine, TX 76051. Directions and lodging information are available at the FMDIC, Inc. Web site at *http://www.fmdic.org/*.

FOR FURTHER INFORMATION CONTACT: Staci McAllister, Consumer Safety Technician, Food and Drug Administration, 4040 N. Central Expressway, Suite 300, Dallas, TX 75204, 214–253–5259, FAX: 214–253–5314, *staci.mcallister@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. This workshop helps achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) as an outreach activity by Government agencies to small businesses.

The goal of the public workshop is to present information that will enable manufacturers and regulated industry to better comply with FDA's medical device requirements. Please visit the *http://www.fmdic.org/* Web site for the agenda and for information about the presenters at the workshop.

II. Participation in the Public Workshop

Registration: FMDIC has early registration ($250 for industry/$150 for government with ID/$50 for students) available until March 14, 2016. Registration after March 14, 2016, increases to $300 for industry, $200 for government with ID, with student registration staying the same, at $50. To register online, please visit *http://www.fmdic.org/*. As an alternative, send the registration information including the registrant's name, title, organization, address, telephone and fax numbers, and email address (for each registrant), along with a check or money order (covering all registration fees) payable to the FMDIC, Inc., to FMDIC Registrar, 4447 N. Central Expressway, Suite 110 PMB197, Dallas, TX 75205. FMDIC, Inc. accepts registrations onsite on the day of the event beginning at 7:30 a.m. at the regular registration fee stated above. Registration on site will be accepted on a space available basis on the day of the public workshop beginning at 7:30 a.m. Please note that due to popularity, similar past events have reached maximum capacity well before the day of the event. The cost of registration at the site is $300 payable to the FMDIC, Inc. The registration fee will be used to offset expenses of hosting the event, including continental breakfast, lunch, audiovisual equipment, venue, materials, and other logistics associated with this event.

If you need special accommodations due to a disability, please contact Staci McAllister (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop.

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04221 Filed 2–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0631]

Requirements for Transactions With First Responders Under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy.'' This guidance describes FDA's compliance policy regarding certain requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) for trading partners engaged in transactions with first responders. This compliance policy is in effect until further notice by FDA.

DATES: Effective February 29, 2016. For information about enforcement dates, please see the **SUPPLEMENTARY INFORMATION** section.

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–D–0631 for ''Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy; Guidance for Industry.'' 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.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). We made this determination because this guidance document provides information pertaining to compliance with certain statutory requirements described in this document that are currently in effect. In addition, because FDA's compliance policy regarding the provisions to provide, capture, and maintain product tracing information under section 582(d)(1) of the FD&C Act (21 U.S.C. 360eee–1(d)(1)) will expire on March 1, 2016 (see 80 FR 67408, November 2, 2015), it is important that FDA provide this information before that date to avoid potential disruptions in the supply chain. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices (21 CFR 10.115(g)(3)). FDA is particularly interested in comments related to the scope of this guidance. FDA will consider any comments received and may revise the scope of the enforcement policy described in this guidance as appropriate.

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law. Section 202 of DSCSA adds sections 581 and 582 to the FD&C Act (21 U.S.C. 360eee and 360eee–1), which set forth new definitions and requirements for the tracing of products through the pharmaceutical distribution supply chain. Starting in 2015, certain trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) generally were required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to exchange product tracing information when engaging in transactions involving certain prescription drugs. These trading partners were also generally required under sections 582(b)(4), (c)(4), (d)(4) and (e)(4) to have systems in place to enable the verification of suspect and illegitimate product. Furthermore, sections 582(b)(3), (c)(3), (d)(3), and (e)(3) specify that the trading partners of manufacturers, wholesale distributors, dispensers, and repackagers must be ''authorized'' within the meaning of section 581(2) of the FD&C Act.

For dispensers, requirements for the tracing of products through the pharmaceutical distribution supply chain under section 582(d)(1) of the FD&C Act took effect on July 1, 2015. FDA published a notice of availability for a revised guidance document on November 2, 2015, stating that it does not intend to take action against dispensers who, prior to March 1, 2016, accept ownership of product without receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act, or do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act (80 FR 67408).

As described in the guidance, FDA understands that transactions between dispensers and first responders may present challenges related to compliance with certain requirements in section 582 of the FD&C Act related to the exchange of product tracing information, conducting business only with authorized trading partners, and having verification systems in place. To minimize possible disruptions to the activities of first responders, FDA does not intend to take action against certain trading partners and first responders as described in the guidance. This compliance policy is in effect until further notice by FDA.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

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

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04227 Filed 2–26–16; 8:45 am]

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