label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911(g) of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

II. Electronic Access

Persons with access to the Internet may access the application documents at: *http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm.*

Dated: November 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25224 Filed 11–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0785]

General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products; 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 guidance for industry entitled ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' This guidance is intended to assist a person who plans to develop and submit an abbreviated new drug application (ANDA) to seek approval of a generic version of a solid oral opioid drug product that references an opioid drug product with abuse-deterrent properties described in its labeling. The guidance recommends studies, including comparative in vitro and pharmacokinetic (PK) studies, that a potential ANDA applicant should conduct and submit to FDA to demonstrate that a generic solid oral opioid drug product is no less abuse deterrent than its reference listed drug (RLD) with respect to all potential routes of abuse.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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)*: Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–0785 for ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drugs; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 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: Gail Schmerfeld, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9291, email: *gail.schmerfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''General Principles for Evaluating the

Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' Prescription opioid analgesics are an important component of modern pain management. However, abuse and misuse of these drug products have created a serious and widespread public health problem. Addressing this public health crisis is an FDA priority. One potentially important step toward the goal of creating safer opioid analgesics has been the development of opioid drug products that are formulated to deter abuse. ''Abuse-deterrent properties,'' as that term is used in the guidance to which this notice applies are those properties shown to meaningfully *deter* abuse; abuse-deterrent properties do not fully *prevent* abuse or addiction. FDA considers the development of these products a high public health priority. It is important that less costly generic versions of opioids that reference listed drugs whose labeling describes abuse-deterrent properties are available to ensure access to safe and effective analgesics for patients who need them.

If the summary in section 9.2 of the approved labeling for the RLD indicates that FDA has concluded that the RLD has properties that are expected to (or have been shown through postmarketing studies to) deter abuse, the potential ANDA applicant should evaluate its proposed generic drug to show that it is no less abuse deterrent than the RLD with respect to *all* of the potential routes of abuse. This will ensure the generic drug is no less abuse-deterrent than the RLD with respect to all potential routes of abuse and minimize the risk of shifting abuse to other, potentially more dangerous routes. This guidance describes FDA's current thinking on the studies that should be conducted by a potential ANDA applicant and submitted to FDA in an ANDA to demonstrate that a generic solid oral opioid drug product is no less abuse deterrent than its RLD with respect to all potential routes of abuse. These studies are in addition to other studies that may be needed to support ANDA approval (*e.g.,* as described in product-specific guidances).

The final guidance, like the draft guidance, focuses on the general principles for developing and evaluating the abuse deterrence of generic solid oral opioid drug products formulated to incorporate physical or chemical barriers, agonist/antagonist combinations, aversive agents, or a combination of two or more of these technologies. FDA will continue to assess the state of science and, as novel technologies develop, will address them by issuing additional guidance, as appropriate.

In the **Federal Register** of March 25, 2016, FDA announced the availability of the draft guidance for industry ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products'' (81 FR 16186). FDA subsequently announced in the **Federal Register** of October 6, 2016, and held on October 31–November 1, 2016, a public meeting to discuss scientific and technical issues relating to formulation development and premarket evaluation of opioid drug products with abuse-deterrent properties (81 FR 69532). This final guidance reflects our consideration of comments made in the dockets for the draft guidance (Docket No. FDA–2016–D–0785) and for the public meeting (Docket No. FDA–2016–N–2896) and comments made during the public meeting, and provides the Agency's current thinking with respect to the general principles for evaluating the abuse deterrence of generic solid oral opioid drug products.

Among other changes, the final guidance eliminates the recommendation to use a control to identify discriminatory study conditions for comparing the proposed generic opioid drug product (the test (T) product) and the RLD (reference (R) product). Instead, FDA recommends that a potential ANDA applicant conduct extraction studies to assess the particular vulnerabilities of T and R products to inform the comparison of their abuse deterrence. The final guidance also provides more detailed recommendations regarding the conduct of in vivo studies, specifically comparative PK studies of manipulated T and R products to evaluate the potential for abuse by the oral and nasal routes of administration.

Appendix 1 of the final guidance continues to describe some of the ways in which the T and R products can be physically manipulated and provides recommendations for conducting extraction studies to assess the particular vulnerabilities of the T and R products to inform the comparison of their abuse deterrence. FDA continues to recommend potential ANDA applicants follow a tier-based approach to extractability testing to efficiently compare a T product to its R product and limit the number of tests required for evaluating the abuse deterrence of the T product, but has modified some of the initial recommendations regarding solvents.

Appendix 2 provides recommendations for evaluating abuse by ingestion. In the final guidance, FDA clarifies the circumstances under which a potential applicant should conduct a comparative oral PK study. Appendices 3, 4, and 5 provide modified recommendations for evaluating abuse by injection, insufflation, and smoking, respectively.

The guidance addresses the general principles for evaluating abuse deterrence in generic solid oral opioid drug products. FDA may provide additional testing recommendations in future product-specific guidances. For example, FDA may recommend in a product-specific guidance that a potential ANDA applicant evaluate human abuse potential (for example, evaluate a study subject's willingness to take drug again) if R product contains a known aversive agent. Further, FDA will continue to assess the state of the science and, as novel technologies develop, will address them by issuing revised or additional guidance, as appropriate.

Potential ANDA applicants may pose questions regarding evaluation of abuse deterrence for a generic solid oral opioid drug product through FDA's pre-ANDA program. The goals of the pre-ANDA program are to clarify regulatory expectations for prospective applicants early in the development process, assist applicants in developing more complete submissions, promote a more efficient and effective ANDA review process, and reduce the number of review cycles required to obtain ANDA approval, particularly for complex products. FDA considers abuse-deterrent opioids to be products that fall within the definition of *complex product* as that term has been defined in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022, which can be found at *https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf.* The pre-ANDA program provides for, among other things, submission of controlled correspondence and requests for formal meetings between FDA and applicants on complex generic drug development issues.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 16, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–25248 Filed 11–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6230]

Tenth Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Tenth Annual Sentinel Initiative Public Workshop.'' The purpose of this 2-day public workshop is to bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Attendees will leave with a deeper understanding of how to use the Sentinel System tools to address safety questions.

DATES: The public workshop will be held on February 7 and 8, 2018. Day 1 of the public workshop will be held on February 7, 2018, from 9 a.m. to 4:30 p.m. Day 2 of the public workshop will be held on February 8, 2018, from 9 a.m. to 2 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at two separate locations. On Day 1 the public workshop will be held at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814. On Day 2 the public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Jamila Mwidau, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 4481, Silver Spring, MD 20993; 301–796–4989, *Jamila.Mwidau@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this 2-day public workshop is to bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Day 1 will be convened by the Duke-Margolis Center for Health Policy at Duke University with support by a cooperative agreement with FDA. Key discussion topics will include an update on the state of FDA's Sentinel Initiative, key safety surveillance activities, and emerging uses of the Sentinel System. In addition, panelists, representing diverse stakeholder perspectives, will provide comments on Sentinel and opportunities to expand its analytic capabilities. This workshop will also provide an opportunity for stakeholder engagement and input on Sentinel's continued modernization.

Day 2 will be a public workshop sponsored by FDA targeting researchers who are experienced in using claims data and will build upon prior public training conducted by FDA on July 10, 2017 (82 FR 19063, April 25, 2017). This second day of the workshop will address more advanced training topics, including Sentinel's inferential analytic capabilities and methods of identifying unexpected safety concerns. Attendees will leave with a deeper understanding of how to use the Sentinel System tools to address safety questions. Attendees are encouraged to review the material FDA presented on July 10, 2017, by visiting the Web site: *https://www.sentinelinitiative.org/communications/sentinel-initiative-events/public-sentinel-training-fda.*

II. Participating in the Public Workshop

Registration: To attend the public workshop, you may register for one or both days, but you must register for each day of the workshop separately. The Duke-Margolis Center for Health Policy at Duke University will manage registration for Day 1 and FDA will manage registration for Day 2.

Day 1: To attend the public workshop on Day 1, you must register before February 6, 2018, by visiting *https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop.* You may also register for the live webcast by visiting this Web page. There will be no onsite registration.

When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. There is no registration fee. However, registration will be on a first-come, first-served basis because seating is limited. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of Hyatt Regency Bethesda. If you need special accommodations due to a disability, please contact Elizabeth Murphy at the Duke-Margolis Center for Health Policy (202–621–2801, email: *elizabeth.g.murphy@duke.edu*) no later than February 6, 2018.

Streaming Webcast for Day 1: The workshop will be webcast (archived video footage will be available following the workshop at *https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop*). Persons interested in viewing the live webcast must register online before February 6, 2018. Early registration is recommended because webcast connections are limited. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements.

All Day 1 event materials will be available to registered attendees via email before the workshop at the Duke-Margolis Web site at *https://healthpolicy.duke.edu/events/10th-annual-sentinel-public-workshop.*

Day 2: To register to attend Day 2 of the workshop in person or virtually via webcast, you must register before February 6, 2018, by visiting: *https://www.eventbrite.com/e/february-8-2018-training-at-fda-tickets-37914164286.*

Please provide complete contact information for each attendee, including name, title, affiliation, telephone number, and email address. Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Lieutenant Commander Jamila Mwidau no later than January 24, 2018.

Streaming Webcast of the Public Workshop Day 2: The FDA training