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**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-1359]

#### Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications; Public Meeting

**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 to discuss the development, assessment, and regulation of abuse-deterrent formulations of opioid medications. The meeting will focus on scientific and technical issues related to the development and in vitro assessment of these products, as well as FDA's approach towards assessing the benefits and risks of all opioid medications, including those with abuse-deterrent properties.

FDA is seeking input on these issues from all stakeholders, including patients, health care providers, the pharmaceutical industry, patient advocates, academics, researchers, and other governmental entities.

**DATES:** The public meeting will be held on October 30, 2014, from 8:30 a.m. to 5 p.m. and October 31, 2014, from 8:30 a.m. to 3 p.m. The public meeting may be extended or may end early depending on the level of public participation. Individuals who wish to present at the meeting must register by October 14, 2014. Individuals who wish to attend the meeting but do not wish to make a presentation should register by October 24, 2014. See section III under the **SUPPLEMENTARY INFORMATION** section for information on how to register to speak at the meeting. Submit

either electronic or written comments by January 9, 2015.

**ADDRESSES:** The public meeting will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800, FAX: 301-587-4791.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-3519, FAX: 301-796-9899, email: [mary.gross@fda.hhs.gov](mailto:mary.gross@fda.hhs.gov); or Brutrinia D. Cain, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4633, email: [Brutrinia.cain@fda.hhs.gov](mailto:Brutrinia.cain@fda.hhs.gov); or Georgiann Ienzi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3515, FAX: 301-847-8737, email: [Georgiann.Ienzi@fda.hhs.gov](mailto:Georgiann.Ienzi@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

Opioid analgesics are important medications that are widely prescribed for the treatment of pain, and certain opioids are also used in drug treatment programs. When used properly, opioid drugs provide significant benefits for patients. However, they also carry a risk of misuse, abuse, addiction, overdose, and death. According to an analysis from the Centers for Disease Control and Prevention (CDC), in 2010, opioid analgesics were involved in 16,651 overdose deaths, which represented a 313 percent increase over the past decade (Ref. 1). The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that for each overdose death, there were an additional 11 treatment admissions (Ref. 2), 33 emergency department visits (Ref. 3), and 880 non-medical users of these drugs (Ref. 4).

The development of and transition to use of opioids with meaningful abuse-deterrent properties is one important component of a multipronged approach to addressing abuse of opioid medications. FDA looks forward to a future in which most or all opioid

medications are available in formulations that are less susceptible to abuse than the formulations that are on the market today.

To achieve this goal, FDA is taking steps to incentivize and support the development of opioid medications with progressively better abuse-deterrent properties. These steps include working with individual sponsors on promising abuse-deterrent technologies, developing appropriate testing methodologies for both innovator and generic products, and publishing guidance on the development and labeling of abuse-deterrent opioids.

FDA understands that the iterative innovation in abuse-deterrent technologies we envision could have implications for generic opioid medications. It is important that generic options remain available to ensure widespread access to effective analgesics for patients who need them.

The transition to abuse-deterrent formulations of opioid medications presents a number of complex scientific and regulatory challenges. The purpose of this public meeting is to share and solicit comments on the Agency's ongoing work to identify and address these challenges.

##### II. Background

Opioid analgesics (e.g., hydrocodone, oxycodone, morphine, and fentanyl) play a vital role in treating both chronic and acute pain. The Institute of Medicine reports that millions of Americans are living with chronic pain, including those suffering from back pain, neuropathic pain, and pain associated with cancer, with an annual economic cost of approximately \$600 billion in health care expenses and lost productivity (Ref. 5). Millions more suffer from acute pain following common medical procedures performed every day across the country, such as dental and orthopedic procedures. While FDA is working to support the efficient development of safer, non-opioid alternatives for treating pain, opioids are currently an indispensable component of the pain treatment armamentarium, and will remain so for some time to come.

Unfortunately, the abuse and misuse of opioid medications has become a public health crisis. Opioid-involved drug overdose death rates in the United States have increased four-fold from 1999 to 2008 (Ref. 6). Emergency department visits, substance abuse treatment admissions, and economic costs associated with opioid abuse have also increased dramatically over the same period (Ref. 7). This rise in adverse events has largely paralleled the

rise in the number of prescriptions for these products (Ref. 7). A comprehensive approach is needed to address this crisis—one that involves other Federal agencies, State governments, professional medical organizations, academic institutions, and other stakeholders. FDA, as one part of the Federal response to this crisis, is working to improve the safe use of opioids.

As part of this work, FDA strongly supports the development of opioid medications with meaningful abuse-deterrent properties. Although this field holds great promise, it is relatively new. Currently available abuse-deterrent formulations are expected to provide improvements over existing formulations, but their impact on the abuse epidemic may be limited. For example, even though some abuse-deterrent technologies have been demonstrated to deter some forms of abuse (e.g., injection or intranasal) to varying degrees in controlled settings, as yet no marketed opioid formulation has been demonstrated to deter the simplest and most common form of abuse—swallowing a number of intact tablets or capsules. Further, all currently available formulations designed to deter abuse can be defeated with sufficient time, equipment, and expertise. These limitations may be impossible to completely overcome as these products must release the opioids they contain to have their intended therapeutic effects.

FDA believes abuse-deterrent technologies can and will improve substantially and can make a real impact in the fight against prescription opioid abuse. FDA hopes that as the market for opioid medications transitions to abuse-deterrent formulations, abuse rates will decrease and the most significant consequences of that abuse (addiction, overdose, and death) will diminish. To that end, fostering the development, marketing, and iterative improvement of abuse-deterrent formulations of opioid medications is a top priority. FDA's work in support of this priority includes the following:

- Established an Opioids Taskforce to coordinate and support FDA work on abuse-deterrent formulations of opioids.
- Consulted with advisory committees in connection with the development, evaluation, and labeling of opioids with abuse-deterrent technologies. For example, in October 2010, a joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee was

held to discuss, among other things, how sponsors should design and conduct postmarket epidemiological or observational studies to evaluate whether and to what extent products designed to reduce the likelihood and incidence of abuse actually do so.

- Issued draft guidance to assist industry in developing and assessing abuse-deterrent opioid formulations ("Draft Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and Labeling," 78 FR 2676; January 14, 2013). FDA participated in the Abuse-Deterrence Formulation Science meeting held on September 30 and October 1, 2013, which provided a forum to discuss the draft guidance. FDA is committed to publishing a final version of this guidance as soon as possible.

- Met and worked with sponsors regarding approval of potentially abuse-deterrent formulations and reviewed applications seeking approval, or, subsequent to such approval, seeking inclusion of language in product labeling regarding the products' purportedly abuse-deterrent properties.

- Determined that the original formulation of OXYCONTIN posed an increased potential for abuse by certain routes of administration compared to reformulated OXYCONTIN. Based on the totality of the data and information available, FDA concluded that the benefits of original OXYCONTIN no longer outweighed its risks. The Agency determined that original OXYCONTIN was withdrawn for reasons of safety and effectiveness, and accordingly will not accept abbreviated new drug applications (ANDAs) that refer to original OXYCONTIN.

- Conducted or supported research on opioid formulations designed to deter abuse. This includes development of in vitro testing methodologies to assess purportedly abuse-deterrent opioid formulations.

- Sought public comment on innovative packaging, storage, and disposal systems that could help deter prescription opioid abuse (see <http://www.gpo.gov/fdsys/pkg/FR-2014-04-09/pdf/2014-07909.pdf>).

### III. Scope of the Public Meeting

FDA is opening a docket and holding a public meeting to obtain public input on issues related to abuse-deterrent formulations of opioid medications. The first session of the meeting will focus on scientific and technical issues related to the development and in vitro assessment of these products. The second session will focus on FDA's

approach to assessing the benefits and risks of the opioids, including opioids with abuse-deterrent properties. The second session will cover both FDA's relevant actions to date as well as how FDA can continue to and further support advances in this field.

#### *A. Session 1: Development and Evaluation of Abuse-Deterrent Opioid Formulations*

In this session FDA personnel and others will give presentations on the manufacturing and formulation science related to abuse-deterrent formulations, including methods used to evaluate the in vitro performance of such formulations. FDA's goal is to develop scientifically rigorous methods for assessing how well purportedly abuse-deterrent opioid formulations—whether submitted in connection with a new drug application (NDA) or an ANDA—actually deter abuse. As discussed in the "Draft Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and Labeling," for NDA products evidence from in vitro studies, bioavailability studies, human abuse liability studies, and/or epidemiological studies may be needed to fully evaluate a product's potentially abuse-deterrent properties. In this session, however, we are focusing only on the first category of testing—in vitro studies.

FDA will discuss its internal research in this area. This discussion will include the manufacturing science behind the design of abuse-deterrent formulations, a variety of manipulation techniques, and the results of testing approved products and placebo formulations under a range of different manipulation conditions. FDA will also discuss results from its research contract with the National Institute for Pharmaceutical Technology and Education on identifying excipient material attributes that impact abuse-deterrent properties. As we will discuss, these results show that while currently available technologies have promise with regard to reducing abuse, additional work is needed, as they also have significant limitations and vulnerabilities.

FDA is developing standardized in vitro test methodologies to assess how well purportedly abuse-deterrent formulations perform under conditions designed to simulate the ways individuals who abuse opioids manipulate opioid products for purposes of abuse (e.g., crushing, heating, dissolving).

For both NDAs and ANDAs, these methodologies could be used to identify the critical performance attributes of the drug potentially related to abuse-deterrence (e.g., crush-resistance, extraction-resistance). For NDAs, these methodologies could be used to assess comparative performance with predecessor products or appropriate controls (e.g., a non-abuse-deterrent immediate-release (IR) formulation with the same active ingredient). For ANDAs, FDA is still considering the best approach, but these methodologies could be used to assess the proposed generic product's critical performance attributes related to abuse deterrence relative to those of the reference listed drug (RLD).<sup>≤</sup>

For both NDAs and ANDAs, FDA intends to issue general guidance defining common protocols for in vitro testing. FDA is considering whether to provide more detailed, product-specific in vitro testing recommendations for ANDAs as well, possibly by including such guidance together with product-specific bioequivalence testing recommendations where appropriate.

#### Topics for Discussion:

- Please comment on the limitations of currently available abuse-deterrent technologies and what next-generation technologies or products might be able to overcome these limitations and provide improved protection against abuse and misuse. Please comment both on the development of iterative improvements in abuse-deterrent technologies for solid oral dose forms of opioids and on the development of abuse-deterrent formulation technologies for non-solid oral dosage forms (e.g., transdermal patches, solutions, and buccal films).

- Please comment on the approach discussed above whereby FDA would focus on a given RLD's critical performance attributes related to abuse deterrence for purposes of evaluating an ANDA referencing that formulation. How would these critical performance attributes be identified for a given product? What if certain attributes are not described in the RLD's approved labeling?

- Please comment on the approach discussed above whereby FDA develops and publishes a standard battery of in vitro test manipulations to be conducted on all, or some appropriate subset of, potentially abuse-deterrent formulations.

- Specifically, please comment on the utility of step-wise testing, moving from simple manipulations to more complex ones. If the abuse-deterrent features are compromised or defeated by simple manipulations, would further

testing that is more complex (e.g., involving more than one manipulation) and more destructive (e.g., higher temperatures, harsher solvents, etc.) be valuable?

- Please also comment on the availability and use of common solvents in which extraction studies should be conducted.

- Please comment on the appropriate controls for in vitro assessments of proposed generic abuse-deterrent formulations. Should the proposed generic abuse-deterrent formulation only be compared with the RLD formulation with abuse-deterrent properties or is the use of an additional negative control necessary to ensure that the test is sufficiently discriminatory? Please comment on the selection and standardization of a negative control, and what degree of superiority compared with the negative control should be viewed as meaningful.

- Please comment on what performance attributes should be considered "critical" in assessing whether and to what extent a formulation effectively deters abuse, such as the time delay or the amount of effort needed by the abuser under controlled conditions to access the drug for purposes of abuse. How can these performance attributes be quantified and linked to their impact on abuse deterrence? For example, an abuse-deterrent technology may only delay—rather than completely prevent—access to the opioid for purposes of abuse. Please comment on the amount of time delay that should be considered significant and the basis for your recommendation.

- Please comment on how FDA should adapt and expand its testing methodologies as new abuse-deterrent technologies become available. Are there any specific emerging technologies that might require new types of testing?

#### *B. Session 2: FDA's Regulation of Abuse-Deterrent Opioid Formulations*

FDA assesses each opioid drug product's safety and efficacy on a case-by-case basis. Abuse potential is one aspect of a product's safety that the Agency considers, together with all other appropriate factors, in determining whether a product's benefits outweigh its risks. As part of this determination, FDA considers the benefit/risk profile of available therapies.

For instance, FDA determined that original OXYCONTIN, which lacked abuse-deterrent properties, posed an increased potential for abuse by certain routes of administration compared to reformulated OXYCONTIN. After

reformulated OXYCONTIN was approved, FDA concluded that the benefits of original OXYCONTIN no longer outweighed its risks. The Agency determined that original OXYCONTIN was withdrawn for reasons of safety and effectiveness, and accordingly will not accept ANDAs that refer to original OXYCONTIN.

Regarding the labeling of opioid products with potentially abuse-deterrent properties, FDA's current thinking is described in the "Draft Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and Labeling." Studies designed to evaluate a product's purportedly abuse-deterrent properties should be scientifically rigorous. In order to support a description of such properties in labeling, the data should predict or show that these properties can be expected to, or actually do, result in a meaningful reduction in that product's abuse potential (Ref. 8). To date, only two products—TARGINIQ and reformulated OXYCONTIN—have obtained labeling for their abuse-deterrent properties consistent with this thinking.

Regarding generic versions of opioids designed to deter abuse, FDA is still carefully considering its approach and much remains to be worked out. See Session 1 above for a discussion of how comparative in vitro testing may be used to assess these products.

As abuse-deterrent technologies continue to improve and new opioid products are developed and approved that meaningfully reduce abuse, FDA expects the market for opioid medications to continue to transition to abuse-deterrent formulations. Ultimately, FDA looks forward to a future in which all or substantially all opioid medications are less susceptible to abuse than the conventional formulations that dominate the market today.

Although FDA has received requests to require all opioid medications, or some subset of them, to be formulated with abuse-deterrent technologies, we have said that a class-wide requirement is not feasible or in the interests of public health at this time (Ref. 9). This field is still in its early stages. Both the technologies involved and the clinical, epidemiological, and statistical methods for evaluating those technologies are new and rapidly evolving. As discussed above, we have limited experience with these formulations and currently available abuse-deterrent technologies have significant limitations.

Accordingly, FDA currently applies the product-by-product approach described in Session 2, with a goal of incentivizing an incremental, sponsor-

driven market transition from conventional opioid formulations to formulations with meaningful abuse-deterrent properties. We anticipate, however, that at some point—after abuse-deterrent formulations have become available for a number of different opioid active moieties and after we have obtained more experience with this field—FDA may determine that the risks of all or most opioid products that lack abuse-deterrent properties outweigh the benefits in light of available therapies. We pose several questions about these approaches below.

Finally, given that currently marketed abuse-deterrent technologies have significant limitations, FDA is interested in appropriately incentivizing and supporting meaningful improvements in abuse-deterrent technologies so that progressively better abuse-deterrent formulations become available. We pose questions about this below as well.

#### Topics for Discussion:

- As described in the “Draft Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and Labeling,” FDA intends to approve language in NDA product labeling that accurately and fairly describes the abuse-deterrent properties of an opioid product if adequately supported by data (Ref. 8). We hope that the availability of such labeling claims will incentivize development and use of those products preferentially where appropriate. Please comment on this approach, including its impact on encouraging the development of generic opioids with abuse-deterrent formulations.

- What does it mean for a product to have meaningful abuse-deterrent properties? Please comment on what data should be provided to support that determination.

- FDA is considering under what circumstances the benefit/risk assessment methodology discussed in Session 2 would support a refusal to approve, or withdrawal of approval for, an NDA for an opioid formulation lacking meaningful abuse-deterrent properties if an available therapy or therapies with meaningful abuse-deterrent properties exist. Please comment on this approach and its implications for the development of abuse-deterrent opioid formulations, patient access to opioid medications, generic competition, and potential drug shortages. What other considerations should pertain?

- One aspect of the benefit/risk assessment relates to the consideration of available therapies. Please comment on FDA’s consideration of available therapies in assessing (or re-assessing)

the benefit/risk profile of an opioid drug product. What product or products should FDA consider to be “available therapies” when assessing or re-assessing the benefit/risk profile of an opioid product?

- Much of the focus in developing abuse-deterrent formulations has been on extended-release and long-acting (ER/LA) opioids. As more ER/LA opioid products are reformulated with abuse-deterrent technologies, individuals who abuse opioids may shift their attention to opioid drugs lacking abuse-deterrent properties, including IR products. Are there special considerations associated with IR products that do not apply to ER/LA opioids? Also, please comment on whether there are subclasses of opioid medications for which a shift to abuse-deterrent formulations may be of limited public health benefit.

- As discussed above, FDA does not think a class-based, abuse-deterrent formulation requirement is feasible or appropriate at this time. Under what circumstances would it be appropriate to impose such a requirement and on what classes or subclasses of opioid products? What considerations should be taken into account to help ensure that such an approach does not conflict with public health needs for continued access to important medications?

- If FDA were to determine that the risks of an opioid product—or, in the case of a class-based approach, many such products—that lacks abuse-deterrent properties outweigh the benefits in light of available therapies, how could the Agency minimize any negative impact on patient access and on generic and innovator drug development? One possible option would be to apply a delayed implementation date (e.g., 2 years) to give affected sponsors a “phase-out” period to either reformulate or withdraw products lacking abuse-deterrent properties. Please comment.

- As noted above, FDA is interested in encouraging the development and introduction of opioid products with progressively better abuse-deterrent properties, as well as the phase-out of products with less meaningful properties, as abuse-deterrent technologies improve. What actions could FDA take to support this goal? Under what circumstances would it be appropriate to refuse to approve or initiate withdrawal of a product with, for example, “first generation” abuse-deterrent properties?

- Finally, FDA is aware of the importance of identifying ways to measure the impacts (positive or negative) of the actions we take to incentivize and support the

development and introduction of abuse-deterrent formulations of opioid medications. Are there specific potential impacts of our actions that we need to consider in addition to those addressed above?

### III. Attendance and Registration

Attendance is free and will be on a first-come, first served basis. Individuals who wish to present at the public meeting must register on or before October 14, 2014, at <https://fda-abuse-deterrent-public-meeting.eventbrite.com>. FDA will accommodate requests to speak, as time permits, and will determine the amount of time allotted to each presenter based on the numbers of speaker requests. Speakers should plan on arriving to the meeting prior to the assigned time in order to avoid forfeiting your assigned time should the agenda move ahead of schedule. An agenda and additional meeting background material will be available approximately 3 days before the meeting at <http://www.fda.gov/Drugs/NewsEvents/ucm408607.htm>.

Individuals who wish to attend the meeting but do not wish to make a presentation should also register at <https://fda-abuse-deterrent-public-meeting.eventbrite.com> by October 24, 2014. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations due to a disability, please contact Mary Gross, Brutrinia Cain, or Georgiann Ilenzi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Information about how to view the live Web cast of this meeting will posted at <http://www.fda.gov/Drugs/NewsEvents/ucm408607.htm>. A video recording of the meeting will be available at the same Web address for 1 year.

### IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. To ensure consideration, submit comments by January 9, 2015. 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. Transcripts

As soon as possible after a transcript of the public meeting is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

## VI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. CDC, "Opioids Drive Continued Increase in Drug Overdose Deaths", 2013, available at [http://www.cdc.gov/media/releases/2013/p0220\\_drug\\_overdose\\_deaths.html](http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html).
2. SAMHSA, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2001–2011. National Admissions to Substance Abuse Treatment Services. BHSIS Series S–65, HHS Publication No. (SMA) 13–4772. Rockville, MD, 2013, available at <http://www.samhsa.gov/data/2k13/TEDS2011/TEDS2011N.pdf>.
3. SAMHSA, Center for Behavioral Health Statistics and Quality, "Drug Abuse Warning Network," 2011, available at [http://samhsa.gov/data/dawn/nations/Nation\\_2011\\_AllMA.xls](http://samhsa.gov/data/dawn/nations/Nation_2011_AllMA.xls).
4. SAMHSA, "Results from the 2012 National Survey on Drug Use and Health," detailed table 1.1A, NSDUH Series H–46, HHS Publication No. (SMA) 13–4795. Rockville, MD, 2013, available at <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf>.
5. Institute of Medicine, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research," available at <http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>.
6. CDC, "Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008," available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm>.
7. Department of Health and Human Services, "Addressing Prescription Drug Abuse in the United States—Current Activities and Future Opportunities," available at [http://www.cdc.gov/HomeandRecreationalSafety/pdf/HHS\\_Prescription\\_Abuse\\_Report\\_09.2013.pdf](http://www.cdc.gov/HomeandRecreationalSafety/pdf/HHS_Prescription_Abuse_Report_09.2013.pdf).
8. "Draft Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and

Labeling," January 2013, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf>.

9. Janet Woodcock, M.D., letter to Center for Lawful Access and Abuse Deterrence et al., dated October 25, 2013, in Docket No. FDA–2013–P–0703, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-0703-0004>.

Dated: September 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–1286]

#### Collaborative Approaches for Medical Device and Healthcare Cybersecurity; 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 the following public workshop entitled "Collaborative Approaches for Medical Device and Healthcare Cybersecurity". FDA, in collaboration with other stakeholders within the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS), seeks broad input from the Healthcare and Public Health (HPH) Sector on medical device and healthcare cybersecurity. The vision for this public workshop is to catalyze collaboration among all HPH stakeholders. Participants will identify barriers to promoting cooperation; discuss innovative strategies to address challenges that may jeopardize critical infrastructure; and enable proactive development of analytical tools, processes, and best practices by the stakeholder community in order to strengthen medical device cybersecurity.

**Dates and Times:** The public workshop will be held on October 21 and 22, 2014, from 9 a.m. to 5 p.m.

**Location:** The public workshop will be held at the National Intellectual Property Rights Coordination Center Auditorium, 2451 Crystal Dr., suite 200, Arlington, VA 22202. Entrance for the public workshop participants is through the main doors which face Crystal Drive. Upon arrival at the facility,

participants should visit the registration table to check in. For parking, participants may choose from a number of pay garages, including one directly beneath the facility.

**Contact Person:** Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5418, Silver Spring, MD 20993, 301–796–6937, FAX: 301–847–8510, email: [Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov).

**Registration:** Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., October 14, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301–796–5661, email: [Susan.Monahan@fda.hhs.gov](mailto:Susan.Monahan@fda.hhs.gov), no later than October 15, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Suzanne Schwartz to register (see *Contact Person*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

**Streaming Webcast of the Public Workshop:** This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 4 p.m., October 14, 2014. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 16, 2014. Most updated browsers will support the Webcast.

**Comments:** FDA is holding this public workshop to obtain information on medical device cybersecurity. In order to permit the widest possible opportunity to obtain public comment,