4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2017-N-6502]

Opioid Policy Steering Committee: Prescribing Intervention--Exploring a Strategy for Implementation; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public hearing entitled, "Opioid Policy Steering Committee: Prescribing Intervention--Exploring a Strategy for Implementation." The purpose of the public hearing is to receive stakeholder input on how FDA might, under its Risk Evaluation and Mitigation Strategy (REMS) authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.

DATES: The public hearing will be held on January 30, 2018, from 8:30 a.m. to 4:30 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to attend, or to present at, the public hearing must register by January 16, 2018. Electronic or written comments will be accepted after the public hearing until March 16, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public hearing will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 B and C), Silver Spring, MD 20993-0002. Entrance for public hearing 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.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered.

Electronic Submissions

Electronic comments must be submitted on or before March 16, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of March 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked, or the delivery service acceptance receipt is, on or before that date.

- 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-2017-N-6502 for "Opioid Policy Steering Committee: Prescribing Intervention--Exploring a Strategy for Implementation; Public Hearing; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), 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.

FOR FURTHER INFORMATION CONTACT: Kathleen Davies, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 2310, Silver Spring, MD 20993, 301-796-2205, kathleen.davies@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On May 23, 2017, the FDA Commissioner announced the establishment of an Opioid Policy Steering Committee (Steering Committee) to explore and develop additional approaches

or strategies FDA could consider using to combat the opioid crisis. Given the unprecedented nature of the opioid crisis and the role of prescription opioids in the crisis, the Steering Committee is considering novel ways to reduce the number of new cases of addiction while continuing to ensure the benefits of opioid products outweigh their risks.

Recent studies suggest that prescriptions for opioid analgesics are frequently dispensed for a number of tablets that exceed those needed for adequate pain control, particularly for acute pain. The Steering Committee is considering whether current prescribing patterns are contributing to the development of new addiction in patients, and whether the excess unused pills are a gateway to misuse, abuse, and addiction among family members and others who might have access to the unused pills. Therefore, the Steering Committee is exploring, by means of FDA's REMS authorities, the option of facilitating appropriate prescribing by requiring sponsors to implement a prescriber intervention at the point when the prescriber determines an opioid analgesic prescription is necessary for a patient. For example, a REMS could impact prescribing by requiring that sponsors ensure that prescribers provide specific documentation for a prescription above a specified amount, such as a statement that the quantity prescribed is medically necessary for the patient. The documentation requirement would not be intended to prevent access for patients in whom chronic use of opioid analgesics is the most appropriate therapy. Instead, it would be designed to ensure that prescribers consider whether the amount prescribed is appropriate for the patient and, if above the specified amount, document that necessity. The Steering Committee's view is that one way sponsors could implement this type of prescribing documentation requirement is through an electronic system at the point of prescribing (i.e., incorporated into the prescriber's workflow) to minimize the burden on patient access and on the health care delivery system. Thus, the Steering Committee is interested in

exploring evidence-based approaches that would encourage electronic prescribing as a mechanism for the prescriber to provide documentation of a safe-use condition (e.g., that the quantity prescribed is medically necessary for the patient) before the drug is dispensed by the pharmacy. The Steering Committee also seeks input from the public on alternative REMS models or approaches for consideration.

II. Topics for Discussion at the Public Hearing

In this public hearing, FDA seeks stakeholder input on new approaches to promote the safe use of opioid analgesics using FDA's REMS authorities. FDA is seeking feedback from a broad group of stakeholders, both private and public, who are working on the challenges of improving pain management while addressing the opioid epidemic. The Agency is also particularly interested in ensuring that any REMS intervention minimizes the burden on patient access and, to the extent practicable, on the health care delivery system. Relevant questions for consideration are provided below.

Prescriber Documentation

Many REMS programs rely on pharmacies to verify that required safe-use conditions have been documented prior to dispensing a drug product. One alternative approach under consideration would require sponsors to ensure that prescribers follow specific requirements outlined in the REMS for each opioid analgesic prescription for a quantity above a specified amount. This approach could involve use of an electronic system (e.g., electronic prescribing integrated into a prescriber's workflow) that would require prescribers to specifically document the medical necessity of the quantity prescribed for a particular patient. This documentation would be verified before the prescription reaches the pharmacy. For prescribers who intend to

prescribe below the specified amount, no additional documentation of medical necessity or electronic prescription would be required.

1. If a REMS were to specify threshold drug amounts for opioid analgesic prescriptions above which prescribers would be required to provide additional documentation of medical necessity, what should the amounts be and how should they be determined for various clinical indications? What data are there to support such amounts? What additional data would be useful?

2. If such measures were required, how should prescribers be made aware of them? Within the Agency's statutory REMS authority, how should the Agency require sponsors to ensure compliance with them? How should the Agency require sponsors to assess their effect in reducing misuse, abuse, and new addictions?

Additional REMS Approaches

Health care providers generally have the capability to access state prescription drug monitoring program (PDMP) data that include patient prescription history and prescribing patterns. PDMPs are separately managed and maintained by the individual states, which may result in disparate data elements and data sharing challenges. Additionally, review of PDMP data requires health care providers to access a database that may not be integrated into their workflow.

Either in conjunction with, or separate from, the prescriber intervention approach discussed above, the Steering Committee is considering whether to require sponsors to create a system that would leverage a nationwide database to be more effective in helping health care providers identify potential misuse and abuse (e.g., doctor shopping) and facilitate safe use of opioid analgesics (e.g., real-time identification of potential harmful drug-drug combinations).

Such an approach could be integrated into the health care provider's workflow to minimize burden on the health care system.

3. The Steering Committee requests input from the public on whether, in addition to, or in conjunction with the above described prescriber intervention, and to the extent consistent with its statutory authority, the Agency should consider requiring sponsors to create a system that utilizes a nationwide prescription history database to facilitate safe use of opioid analgesics.

4. If this approach were adopted, how should the Agency require sponsors to assess the impact of such requirements?

Additional Considerations

The Steering Committee acknowledges that the approaches described above emphasize specific components within the opioid prescribing pathway and might not address other areas where misuse and abuse may be occurring. The Steering Committee seeks input from the public on additional approaches the Agency may consider, within its statutory authority, to reduce misuse, abuse, and addiction associated with opioid analgesics.

5. The proposed Opioid Analgesics REMS includes a Medication Guide and a Patient Counseling Document to educate patients. It also includes a *Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain* that contains information on counseling patients and caregivers about the safe use of opioid analgesics. Consistent with its statutory authority, should FDA require sponsors to take additional measures to ensure that health care providers, their patients, and patient caregivers and family members are educated on safe storage and disposal and the risks of misuse, abuse, and addiction associated with opioid analgesics (e.g., a public health campaign targeted at these groups)?

6. Should the Agency consider additional measures intended to improve the safety of patient storage and handling of opioid analgesics?

7. How might use of unit-of-use packaging play a role in encouraging appropriate prescribing of opioid analgesics?

8. Should the Agency require sponsors to create a mechanism by which patients could return unused pills, and if so, to whom?

III. Participating in the Public Hearing

Registration: The FDA Conference Center at White Oak is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend, either in person or by webcast (see *Streaming Webcast of the Public Hearing)*, and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments at https://www.eventbrite.com/e/opioid-policy-steering-committee-tickets-39490940466 by January 16, 2018, and provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the question, or questions, they wish to address. This will help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will notify registered presenters of their scheduled presentation times. Time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation (.DOC, .DOCX, .PPT, .PPTX, .XLS, .XLSX, .PDF formats preferred) to kathleen.davies@fda.hhs.gov on or before January 22, 2018. No commercial or

promotional material will be permitted to be presented or distributed at the public hearing. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and any other background materials will be made available 3 days before the hearing at https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm.

If you need special accommodations due to a disability, please contact Kathleen Davies at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: This public hearing will also be webcast for those unable to attend in person. To join the hearing via the webcast, please go to https://collaboration.fda.gov/opsc.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public hearing is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

IV. Notice of Public Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding

officer, accompanied by FDA senior management from the Office of the Commissioner and the relevant centers/offices. Under § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section V). To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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