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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1646]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 11, 2019, from 8 a.m. to 5 p.m. and June 12, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2019-N-1646. The docket will close on June 30, 2019. Submit either electronic or written comments on this public meeting by June 30, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 30, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2019. 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.

Comments received on or before May 28, 2019, will be provided to the committees. Comments received after that date will be taken into consideration by FDA.

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-2019-N-1646 for "Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see the **ADDRESSES** section) 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." FDA 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 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 the 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: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: DSaRM@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the

FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: FDA is seeking public input on the clinical utility and safety concerns associated with the higher range of opioid analgesic dosing (both in terms of higher strength products and higher daily doses) in the outpatient setting. FDA is interested in better understanding current clinical use and situations that may warrant use of higher doses of opioid analgesics. We are also interested in discussing the magnitude and frequency of harms associated with higher doses of opioid analgesics relative to lower doses, as well as optimal strategies for managing these risks while ensuring access to appropriate pain management for patients.

FDA frequently hears from patients and healthcare providers that higher-dose opioid analgesics continue to be a unique and necessary part of effective pain management for some patients. FDA is also cognizant of serious safety concerns associated with both higher strengths and higher daily doses of opioid analgesics, both in patients and in others who may access these drugs. Higher strength products may be more harmful in cases of accidental exposure and overdose and may also be more sought out for misuse and abuse. Along with a number of other factors, a higher daily opioid dose is associated with greater risk of overdose. Concerns have also been raised that higher dose opioid regimens may carry a higher risk of addiction, although robust evidence for a causal relationship is lacking. There is a strong association between higher opioid dose and duration/persistence of opioid analgesic therapy and assessing temporal relationships and independent effects of opioid dose and duration on the risks of both addiction and overdose is challenging. In addition, FDA acknowledges the complex and evolving landscape of the opioid epidemic, with myriad Federal, State, local, and payer efforts to encourage more judicious prescribing of opioid analgesics, and the growing threat of highly lethal illicit opioids.

To better understand both the clinical utility and harms of higher dose opioid analgesics in the current environment, and to discuss the advantages and disadvantages of various potential risk-management strategies, FDA brings these issues to an advisory committee to

seek input and advice from the clinical, patient, public health, and research communities.

In particular, FDA seeks to discuss: (1) The current clinical use and situations that may warrant pain management with opioid analgesics at higher product strengths and daily doses, factors influencing prescribing practices, and specific patient populations for whom there may be utility in prescribing these medications at higher doses; (2) the magnitude and frequency of harms associated with opioid analgesics at higher product strengths and daily doses, relative to lower strengths and daily doses, including the role of opioid dose in adverse health outcomes in both patients and in others who may access the drugs (e.g., risk for developing addiction, fatal overdose), the relevance of therapy duration and physical opioid dependence, and risks in different subpopulations (e.g., patients with chronic non-cancer pain, young children, adolescents); and (3) possible FDA interventions and their expected impact on patients and public health more broadly, including, for example, potential effects on prescribing and pain management practices, patient experience and behaviors, and adverse outcomes such as addiction and overdose.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 12:30 p.m. on June 12, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 17, 2019. Time allotted for each presentation may be limited. If

the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 20, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2018-N-2027; FDA-2012-N-0961; FDA-2018-N-3037; FDA-2014-N-1721; FDA-2005-N-0101; FDA-2012-N-0294; FDA-2011-N-0449; FDA-2018-N-3404; FDA-2018-N-3552; and FDA-2018-N-2969]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.