DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2904]

Expanding Access to Effective Treatment for Opioid Use Disorder: Provider Perspectives on Reducing Barriers to Evidence-Based Care; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting entitled ''Expanding Access to Effective Treatment for Opioid Use Disorder: Provider Perspectives on Reducing Barriers to Evidence-Based Care.'' Convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA, the public meeting is intended to generate a discussion with providers and health system stakeholders on the armamentarium of medications to treat opioid use disorder (OUD), current barriers to appropriate use of these medications, opportunities to further reduce stigma, and methods to expand access to effective pharmacotherapies as part of an evidence-based approach to OUD treatment.

DATES: The public meeting will be held on September 20, 2018, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the National Press Club, 529 14th St. NW, Washington, DC 20045. For additional travel and hotel information, please refer to the following web page: *https://healthpolicy.duke.edu/events/expanding-access-to-treatment-for-OUD.* There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Meeting*).

FOR FURTHER INFORMATION CONTACT: Mitra Ahadpour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4546, Silver Spring, MD 20993–0002, 301–796–8469, *Mitra.Ahadpour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The opioid epidemic remains a growing public health crisis. FDA efforts to address the opioid crisis have included, among other things, revision of the document entitled ''FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain'' (*https://www.fda.gov/Drugs/NewsEvents/ucm553931.htm*), to support rational prescribing, packaging, storage, and disposal of opioids; stemming illegal opioid sales; expanding the Risk Evaluation and Mitigation Strategy to cover immediate-release opioid formulations; monitoring the abuse potential of marketed opioids and taking regulatory action as needed; and addressing barriers to new drug development for non-opioid alternative treatment of pain. Despite these efforts and those of others, opioid misuse, OUD, and overdose remain major public health challenges (Refs. 1 and 2).

Over 2.1 million persons aged 12 or older suffer from opioid use disorders related to prescription opioid analgesics or heroin (Ref. 2), and the majority of those suffering from OUD still lack access to evidence-based treatment. Although there is no one-size-fits-all approach to OUD treatment, there is strong evidence demonstrating the effectiveness of FDA-approved medications, combined with counseling and behavioral therapies, for these patients. Promoting the wider use of these safe and effective therapies is a key priority of FDA. However, substantial challenges remain in patient access and provider use of medications for OUD treatment.

This public meeting is intended to serve as a platform to engage in and generate an active discussion with provider communities and health system stakeholders on the armamentarium of medications to treat OUD, barriers to appropriate use of these medications, opportunities to further reduce stigma, and methods to expand access to effective OUD treatment.

II. Topics for Discussion at the Public Meeting

During the public meeting, speakers and participants will cover issues related to expanding access to effective treatment for OUD, specifically in regard to provider perspectives on reducing barriers to evidence-based care. Topics will include, but are not limited to, the following:

- The role of FDA and the Department of Health and Human Services in confronting and combatting the opioid epidemic;
- The current state of knowledge on addiction, clinical approaches for identifying and assessing OUD, and use of medication-assisted treatment;
- Gaps in the pharmacological armamentarium for treating OUD, including shortfalls or unmet needs that should be considered in developing new therapies;
- Innovative and evidence-based approaches to OUD treatment delivery, lessons learned, and challenges to broader implementation;
- Legal, regulatory, and cultural barriers to access for treatment for OUD and potential opportunities to reduce stigma and expand access to effective OUD treatment;
- Care models and challenges for increasing access to OUD treatment for vulnerable and medically underserved populations; and
- Clinical, health system, and economic perspectives on defining successful outcomes for OUD treatment, including how establishing outcome measures may facilitate quality improvement, innovative payment approaches, and access to effective care.

During meeting sessions, audience and webcast participants will be invited to actively participate in the discussion regarding provider and clinical expert perspectives on treatment for OUD and barriers to care.

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online at *https://healthpolicy.duke.edu/expanding-access-to-treatment-for-OUD* by September 19, 2018, by 5 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

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. Registrants will receive confirmation when the registration has been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (202–791–9561, *sarah.supsiri@duke.edu*) no later than September 13, 2018.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast, and archived video footage will be available at the Duke-Margolis

Center's website following the meeting: *https://healthpolicy.duke.edu/events/expanding-access-to-treatment-for-OUD.* Webcast participants will be able to submit questions and comments via the webcast portal. Persons interested in participating in the live webcast must register online by September 19, 2018, by 5 p.m. Eastern Time (see *Registration* section above). Early registration is recommended because webcast connections are limited. Organizations are required to register all participants; however, we request that organizations view the meeting using one connection per location whenever possible.

Other Issues for Consideration: All event materials will be provided to registered attendees via email prior to the meeting and will be made publicly available at the Duke-Margolis Center's website: *https://healthpolicy.duke.edu/events/expanding-access-to-treatment-for-OUD.* A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Conference Center.

IV. References

The following references are on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Hedegaard, H., M. Warner, and A.M. Miniño, ''Drug Overdose Deaths in the United States, 1999–2016,'' NCHS Data Brief, no. 294, Hyattsville, MD: National Center for Health Statistics. 2017 (available at *https://www.cdc.gov/nchs/products/databriefs/db294.htm*), accessed June 27, 2018.
2. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, ''Results from the 2016 National Survey on Drug Use and Health: Detailed Tables.'' September 8, 2016 (available at *https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.htm*), accessed June 27, 2018.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0449]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sun Protection Factor Labeling and Testing Requirements for Over-the-Counter Sunscreen Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on sun protection factor (SPF) labeling and testing requirements for over-the-counter (OTC) sunscreen products containing specified ingredients and marketed without approved applications, and comments on compliance with Drug Facts labeling requirements for all OTC sunscreen products.

DATES: Submit either electronic or written comments on the collection of information by October 22, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 22, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 22, 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.

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–2011–N–0449 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products.'' 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