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.

ADDRESS: 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-OU.

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-OU 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...
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, 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 may be 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