Instructions: All submissions received must include the Docket No. FDA–2017–N–1957 for ''Medical Imaging Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management 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 Division of Dockets Management. 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: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, 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: *MIDAC@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 Agency's Web site at *http://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: The committee will discuss new drug application (NDA) 208–630 for 5-Aminolevulinic Acid Hydrochloride [5–ALA HCl], Powder, for oral solution, submitted by NX Development Corp., for the proposed indication as an imaging agent to facilitate the real time detection and visualization of malignant tissue during glioma surgery.

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 Web site 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 Web site after the meeting. Background material is available at *http://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 committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before April 26, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 April 18, 2017. 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 April 19, 2017.

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

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 special accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–07767 Filed 4–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1094]

Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics—Exploring the Path Forward; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: As part of the work by the Federal Government to address the epidemic of prescription and illicit opioid abuse, the Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop to obtain input on issues and challenges associated with Federal efforts to support training on pain management and the safe prescribing, dispensing, and patient use of opioids (safe use of

opioids) for health care providers. As discussed in this document, the workshop has three main goals. First, participants will be asked to discuss the role that health care provider training plays, within the broader context of ongoing activities, to improve pain management and the safe use of opioids. Second, participants will be asked to comment on how best to provide health care providers, who prescribe or are directly involved in the management or support of patients with pain, appropriate training in pain management and the safe use of opioids. Finally, participants will be asked about the issues and challenges associated with possible changes to Federal efforts to educate health care providers on pain management and the safe use of opioids.

Participants are expected to include individuals from a broad set of Federal, State, and private stakeholder groups that are working on the challenges of improving pain management while addressing the opioid abuse epidemic. The Federal Agencies participating include FDA, the Drug Enforcement Administration, the Department of Veterans Affairs, the Centers for Disease Control and Prevention, the Department of Defense, the Centers for Medicare & Medicaid Services, the National Institute on Drug Abuse, and the Substance Abuse and Mental Health Services Administration, and the Indian Health Service. Public participation and comment are encouraged.

DATES: The public workshop will be held on May 9 and 10, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by July 10, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 10, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 10, 2017. 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. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 877–298–2066.

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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–1094 for ''Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics —Exploring the Path Forward; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6178, Silver Spring, MD 20993–0002, 301–796–3519, email: *Mary.Gross@fda.hhs.gov;* or Doris Auth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2480, Silver Spring, MD 20993–0002; 301–796–0487, email: *Doris.Auth@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 12, 2012, FDA approved a risk evaluation and mitigation strategy (REMS) for extended release (ER) and long-acting (LA) opioid analgesic medications (ER/LA Opioid Analgesics REMS). The goal of such REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of extended-release or long-acting (ER/LA) opioid analgesics while maintaining patient access to pain medications.

Adverse outcomes of concern include addiction, unintentional overdose, and death. The ER/LA Opioid Analgesics REMS requires that prescriber training in the form of accredited continuing education be made available to health care providers who prescribe ER/LA opioid analgesics.

On May 3 and 4, 2016, FDA convened a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss whether this REMS assures safe use of these products, whether it is not unduly burdensome to patient access to the drugs, and whether it (to the extent practicable) minimizes the burden to the health care delivery system (*https://www.gpo.gov/fdsys/pkg/FR-2016-03-14/pdf/2016-05573.pdf*). FDA sought input on possible modifications to the ER/LA Opioid Analgesic REMS, including expansion of the scope and content of prescriber training and expansion of the REMS program to include immediate release (IR) opioid analgesics. The majority of committee members were in favor of modifying the REMS program to include the IR opioid analgesics as well as broadening the training program to include pain management. Though the majority of the committee members were in favor of a requirement for all prescribers to complete training, they recommended that the required training program be implemented through mechanisms outside of the FDA REMS authority. The committees also stated that other health care providers involved in the management of pain should be included as a target audience for education, though they did not specify that the training should be mandatory for non-prescribing health care providers.

In addition to the joint Advisory Committee advice on prescriber education, a Request for Information (RFI) was posted by the Department of Health and Human Services (HHS) Assistant Secretary of Planning and Education on July 8, 2016 (81 FR 44640), seeking comment on the most promising approaches in prescriber education and training programs and effective ways to leverage HHS programs to implement/expand them. The 2017 public workshop on May 9 and 10 seeks to build on one of the requests outlined in that RFI, specifically, the request for suggestions of additional activities HHS and its federal partners could implement to support universal prescriber education on appropriate pain management and opioid analgesic prescribing.

II. Topics for Discussion at the Public Workshop

On May 9 and 10, 2017, FDA on its own behalf and in conjunction with the other participating federal agencies will hold a public workshop and convene government experts, representatives from State licensing boards, professional associations, health care systems, patient groups, and other relevant stakeholder groups. The workshop has three major goals. First, participants will be asked to discuss the role that health care provider training plays, within the broader context of ongoing activities, to improve pain management and the safe use of opioids. Second, participants will be asked to comment on how best to provide health care providers, who prescribe or are directly involved in the management or support of patients with pain, appropriate training in pain management and the safe use of opioids. As a part of this discussion, current training efforts by States, hospitals and health care systems, Federal Agencies, professional associations and other groups will be considered in order to strategize how best to facilitate training for these health care providers. Finally, participants will also be asked about issues and challenges associated with possible changes to Federal efforts to educate health care providers on pain management and the safe use of opioids.

Participants include individuals from a broad set of Federal, State, and private stakeholders that are working on the challenges of improving pain management while addressing the opioid abuse epidemic. The Federal Agencies participating include FDA, the Drug Enforcement Administration, the Department of Veterans Affairs, the Centers for Disease Control and Prevention, the Department of Defense, the Centers for Medicare & Medicaid Services, the National Institute on Drug Abuse, the Substance Abuse and Mental Health Services Administration, and the Indian Health Service. Public participation and comment is encouraged.

Panels will be drawn from Federal and State agencies, as well as other private and public groups working to address pain management and/or opioid abuse. During the panel discussions, panelists will be asked to address the following:

(1) The relative role of Federal training/education efforts in the larger landscape of activities aimed at improving pain management, including the use of opioid analgesics. This includes a discussion of ongoing efforts being led by States, hospitals and health care systems, other Federal Agencies, and medical societies that focus on other aspects of the issue, such as Prescription Drug Monitoring Programs.

(2) The merits and challenges of utilizing Federal mechanisms to provide education on pain management and the safe use of opioid analgesics. This includes a discussion of the role, if any, of mandatory Federal education efforts.

(3) The merits and challenges of utilizing non-Federal mechanisms to provide education on pain management and the safe use of opioid analgesics. This includes a discussion of current State and other efforts and the role they are playing in training/education on pain management and the safe use of opioid analgesics.

(4) The merits and challenges of utilizing partnerships between Federal Agencies and other groups to provide education on pain management and the safe use of opioid analgesics. This includes a discussion of the role of the Federal Government in formal public-private partnerships or other combined approaches to training/education on pain management and the safe use of opioid analgesics for all prescribers. It also includes a discussion of the appropriate organizations (*e.g.,* Federal Agency, State medical board, other) to include in such efforts.

(5) The aspects of the opioid epidemic that can be most impacted by the training of health care providers and how outcomes of these training programs can be measured.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online by sending an email to *https://nakamotoevents.wufoo.com/forms/p1gsrzm80gd7lkd/* before May 1, 2017. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by May 1, 2017. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when their registration has been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Mary Gross or Doris Auth (see **FOR FURTHER INFORMATION CONTACT**) no later than May 1, 2017.

Requests for Oral Comments: During online registration you may indicate if you wish to provide a statement during the Open Public Comment Period. We will do our best to accommodate requests to make public comments based on time allocated for public comment. Individuals and organizations with common interests are urged to consolidate or coordinate their comments, and request time for a joint presentation. Following the close of registration date, we will determine the amount of time allotted to each commenter and the approximate time each oral comment is scheduled to begin; commenters should arrive ahead of their scheduled time in case the agenda moves ahead of schedule so as to be sure not to forfeit their speaking time. All requests to make oral comments must be received by the close of registration on May 1, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Additional information will be made available regarding accessing the Webcast 2 days prior to the public workshop at *http://www.fda.gov/Drugs/NewsEvents/ucm538047.htm.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see ADDRESSES). A link to the transcript will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm538047.htm.*

Dated: April 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–07821 Filed 4–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1989]

Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, in co-sponsorship with the Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium, is announcing a public workshop entitled ''Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials.'' The purpose of the public workshop is to provide a forum for collaborative multidisciplinary discussion to identify opportunities and address challenges for clinical outcome assessments, particularly patient-reported outcome (PRO) assessments, in oncology drug development. In this public workshop, a broad array of international stakeholders involved in oncology drug development and PRO measurement will provide perspectives on the role of PRO measures to provide complementary clinical data on the symptomatic side effects of anti-cancer agents. Speakers and panelists will explore the utility of information derived from existing and emerging PRO measures and discuss potential ways to improve the collection, analysis, and presentation of the data to support drug development and better inform treatment decisions. In addition, workshop participants will discuss possible approaches to the patient-reported assessment of an investigational drug's overall side effect burden as a clinical trial endpoint. This public workshop will include speakers and panelists from regulatory agencies, academia, patient advocacy groups, and the medical product industry.

DATES: The public workshop will be held on April 25, 2017, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Ave., Bethesda, MD 20814, 301–657–1234.

FOR FURTHER INFORMATION CONTACT: Theresa Hall, Patient-Reported Outcome Consortium, Critical Path Institute, 1730 East River Road, Tucson, AZ 85718, 520–777–2875, FAX: 525–547–3456, email: *thall@c-path.org;* and Valerie Vashio, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3710, FAX: 301–796–9909, email: *valerie.vashio@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Clinical outcome assessment (COA) tools are intended to capture how patients experience a disease and its treatment by assessing symptoms, function, and other aspects of a patient's health-related quality of life (HRQL). PRO measures are one important type of COA tool. There is growing interest in optimizing the use of PRO measures to better incorporate the patient perspective into oncology drug development. While PRO measures can be used to evaluate the efficacy of cancer treatments, there is increasing interest in the use of PRO tools to assess symptomatic side effects of treatment. New PRO item banks and libraries are becoming available that can provide needed flexibility to tailor the PRO assessment to the wide range of side effects seen with the various mechanistic classes utilized in contemporary drug development. FDA is interested in gaining feedback on methods to integrate the patient into the assessment of safety and tolerability of cancer drugs through systematic patient-reporting of side effects during clinical trials. This public workshop will discuss standard clinician reporting of adverse events, the development and implementation of the PRO-Common Terminology Criteria for Adverse Events (CTCAE) assessment tool, and explore different analysis and presentation methods for longitudinal patient-reported adverse event data.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this public workshop. The registration fee is charged to help defray the costs of the public workshop facility, speaker and panelist expenses, audiovisual equipment, materials, and food. Persons interested in attending this public workshop must register by April 21, 2017. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. Seats are limited, and registration will be on a first-come, first-served basis.

To register for the public workshop, please complete registration online at *https://www.cvent.com/events/second-annual-workshop-on-clinical-outcome-assessments-coas-in-cancer-clinical-trials/registration-270d8a5ee3ae4a108938851e2a7d0ea7.aspx.* (FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives.	$400.
Charitable Nonprofit/ Academic.	$100 (Contact C-Path).