

Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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.” 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 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 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: Lauren D. Tesh, 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: AMDAC@fda.hhs.gov, or the 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 FDA’s Web site 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: The committee will discuss new drug application (NDA) 209367, ciprofloxacin inhalation powder, sponsored by Bayer HealthCare Pharmaceuticals, Inc., for the proposed indication of reduction of exacerbations in non-cystic fibrosis bronchiectasis (NCFB) adult patients (≥18 years of age) with respiratory bacterial pathogens.

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 <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 committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before November 1, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 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 October 24, 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 October 25, 2017.

Persons attending FDA’s advisory committee meetings are advised that FDA 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 Lauren D. Tesh 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 <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.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: September 26, 2017.

Anna K. Abram,

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

[FR Doc. 2017-20949 Filed 9-28-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5608]

Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to solicit suggestions, recommendations, and comments from interested parties, including patients and patient representatives, health care professionals, academic institutions, regulated industry, and other interested organizations, on questions relevant to FDA’s newly established Opioid Policy Steering Committee (OPSC). Opioid addiction and the resulting overdoses and deaths have created a national crisis, which requires action by federal agencies that may in some instances be unprecedented in order to address the situation and attempt to turn the tide on the crisis. As a public health agency

responding to the crisis, FDA seek public input as it considers how its authorities can or should be used to address this crisis. This information will help the Agency understand areas of focus important to the public and identify and address opioid product and policy issues that need clarification. FDA is especially interested in hearing from interested parties in three key areas: What more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions; what steps can FDA take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice; and should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?

DATES: Submit either electronic or written comments by December 28, 2017.

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 December 28, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 28, 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.

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-2017-N-5608 for "Opioid Policy Steering Committee; 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 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 "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, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 2310, Silver Spring, MD 20993, 301-796-2205.

SUPPLEMENTARY INFORMATION: On April 19, 2017, the Secretary of Health and Human Services announced the HHS strategy for fighting the opioid crisis. The five point strategy includes: (1) Improving access to prevention, treatment, and recovery services; (2) targeting availability and distribution of overdose-reversing drugs; (3) strengthening timely public health data and reporting; (4) supporting cutting-edge research; and (5) advancing the practice of pain management. Following that announcement, on May 23, 2017, the Commissioner of Food and Drugs announced his intention to take more forceful steps to combat the opioid crisis. An OPSC was established to explore and develop additional tools or strategies FDA can use to confront this crisis. The OPSC has a broad mandate to consider steps that FDA can take to confront the opioid crisis. FDA is seeking suggestions, recommendations, and comments from interested parties, including patients and patient representatives, health care professionals, academic institutions, regulated industry, and other interested organizations, with regard to a number of topics related to three overarching questions: (1) What more can or should FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions; (2) what steps can or should FDA take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice; and (3) should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?

I. Assessing Benefit and Risk in the Opioids Setting

In a July 6, 2017, article in the *Journal of the American Medical Association*, FDA explained its approach to assessing the benefits and risks of drug products, describing a structured approach that, in the case of opioids, includes extensive additional review of the risks related to the potential misuse and abuse of these products. FDA explained that it is working to incorporate the effects of decisions on public health into its benefit-risk framework in a more quantitative manner that can supplement and enhance the strong qualitative work that the Agency already performs (Ref. 1). In addition, in March 2016, FDA commissioned a study from the National Academies of Sciences, Engineering, and Medicine to outline the state of the science regarding prescription opioid abuse and misuse, the evolving role that opioid analgesics play in pain management, and additional actions FDA should consider to address the opioid crisis with particular emphasis on strengthening its benefit-risk framework for opioids. That report was issued in July (Ref. 2). While FDA considers the report recommendations, we would like to solicit additional feedback that will supplement those recommendations.

Specific questions on which FDA seeks comment relating to this topic are as follows:

1. How should FDA tailor, or otherwise amend, its assessment of benefit and risk in the context of opioid drugs to ensure that the Agency is giving adequate consideration to the risks associated with the labeled indication of these drugs and the risks associated with the potential abuse and misuse of these products?

2. Are there specific public health considerations other than misuse and abuse that FDA should incorporate into its current framework for benefit and risk assessment as a way to reduce the opioid addiction epidemic? That framework includes, but is not limited to, how FDA makes regulatory decisions to approve new opioids, evaluates their use in the postmarket setting, or limits or influences their prescribing through product labeling or other risk management measures.

II. Steps To Promote Proper Prescribing and Dispensing

Proper prescribing and dispensing are critical to successfully reducing opioid misuse and abuse. A 2016 Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain* reported that, “[w]hen

opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.” (Ref. 3.) And a recent analysis showed that, across six studies of patients who had undergone a variety of surgical procedures, 67 percent to 92 percent of patients reported unused opioid analgesics. Moreover, “[r]ates of safe storage and/or disposal of unused opioids were low,” resulting in an “important reservoir of unused opioids available for nonmedical use” (Ref. 4). There are clinical situations that may require a supply of opioid analgesics that exceeds current CDC guidelines and FDA wants to make sure that patients have what they need in those cases. But FDA believes there are situations in which patients are prescribed an opioid analgesic when a non-opioid pain treatment would be adequate or, when an opioid product is necessary, treatment with a shorter course of therapy would be more appropriate, and without specific requirements, variance in prescribing habits are likely to persist.

Specific questions on which FDA seeks comment relating to this topic are as follows:

1. Should FDA consider adding a recommended duration of treatment for specific types of patient needs (e.g., for specific types of surgical procedures) to opioid analgesic product labeling? Or, should FDA work with prescriber groups that could, in turn, develop expert guidelines on proper prescribing by indication?

2. If opioid product labeling contained recommended duration of treatment for certain common types of patient needs, how should this information be used by FDA, other state and Federal health agencies, providers, and other intermediaries, such as health plans and pharmacy benefit managers, as the basis for making sure that opioid drug dispensing more appropriately and consistently aligns with the type of patient need for which a prescription is being written?

3. Are there steps FDA should take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice?

4. Are there other steps that FDA should take to help promote the prescribing of treatment durations that are appropriately tailored to a clinical patient need?

III. Requirements for Prescriber Education

Recently, the option of mandating education or training for health care professionals who prescribe opioid medications has been more widely discussed,¹ and some states already are, or are considering, mandating such prescriber education. For example, as of July 1, 2017, health care professionals in New York State who are licensed to prescribe controlled substances must complete, and register their completion of, at least 3 hours of course work or training in pain management, palliative care, and addiction (Ref. 5).

Specific questions on which FDA seeks comment relating to this topic are as follows:

1. Are there circumstances under which FDA should require some form of mandatory education for health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations, understand how to identify the risk of abuse in individual patients, know how to get patients with a substance use disorder into treatment, and know how to prescribe treatment for—and properly manage—patients with substance use disorders, among other educational goals? Are there other steps FDA could take to educate health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations?

2. How might FDA operationalize such a requirement if it were to pursue this policy goal? For example, should mandatory education apply to all prescribing health care professionals, or only a subset of prescribing health care professionals? If only a subset, how would FDA construct a framework that focuses mandatory education on only that subset—for example, by requiring mandatory education only for those writing prescriptions for longer durations as opposed to those for very short-term use?

3. What steps should FDA take to make implementing such mandatory education efficient and more feasible? For example, should FDA work collaboratively with state public health agencies, state licensing boards, provider organizations, such as medical specialty societies and health plans, or with other stakeholders, such as

¹ FDA acknowledges the Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee Meeting, held May 3–4, 2016, discussed mandatory education for health care professionals (Docket No. FDA–2016–N–0820).

pharmacy benefit managers, to integrate or avoid duplicating their educational programs or requirements? What other steps might FDA consider to make implementation less burdensome and more effective?

IV. Additional Matters for Consideration

1. What other steps should FDA take to operationalize the above described goals?
2. Are there additional policy steps FDA should consider relating to the OPSC that are not identified in this notice?

We invite interested parties to review these questions and submit comments to the docket for the OPSC to consider. In addition, we invite interested parties to submit additional policy considerations or recommendations for actions that FDA could or should undertake to help the Agency better address the opioid addiction crisis.

V. References

1. Gottlieb, Scott and J. Woodcock. "Marshaling FDA Benefit-Risk Expertise to Address the Current Opioid Abuse Epidemic." *Journal of the American Medical Association*. 2017;318(5):421–422. Doi:10.1001/jama.2017.9205. Available at <http://jamanetwork.com/journals/jama/fullarticle/2644333>. Accessed August 2017.
2. National Academies of Sciences, Engineering, and Medicine. "Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use (2017), Consensus Study Report." Richard J. Bonnie, Morgan A. Ford, and Jonathan K. Phillips (eds.). Available at <https://www.nap.edu/catalog/24781/pain-management-and-the-opioid-epidemic-balancing-societal-and-individual>. Accessed August 2017.
3. Dowell, D., T. M. Haegerich, and R. Chou. "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016." Item 6 in "Determining When to Initiate or Continue Opioids for Chronic Pain." *Morbidity and Mortality Weekly Report Recommendations and Reports* 2016;65(No. RR–1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.r6501e1>. Accessed August 2017.
4. Bicket, M. C., J. J. Long, P. J. Pronovost, et al. "Prescription Opioid Analgesics Commonly Unused After Surgery, A Systematic Review." *JAMA Surgery*. Published online August 2, 2017. DOI:10.1001/jamasurg.2017.0831. Available at <http://jamanetwork.com/journals/>

jamanetwork.com/journals/jamasurgery/fullarticle/2644905. Accessed August 2017.

5. New York State Department of Health, Mandatory Prescriber Education. Available at https://www.health.ny.gov/professionals/narcotic/mandatory_prescriber_education/. Accessed August 2017.

Dated: September 26, 2017.
Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
 [FR Doc. 2017–20905 Filed 9–28–17; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
[HHS–OS–0990–0281–60D]

Agency Generic Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 28, 2017.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0281–60D and project title for reference, to the Report Clearance Officer, Sherrette Funn.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity

of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Prevention Communication Formative Research—Revision—OMB No. 0990–0281.

Abstract: The Office of Disease Prevention and Health Promotion (ODPHP) is focused on developing and disseminating health information to the public. ODPHP faces an increasingly urgent interest in finding effective ways to communicate health information to America’s diverse population. ODPHP strives to be responsive to the needs of America’s diverse audiences while simultaneously serving all Americans across a range of channels, from print to new communication technologies. To carry out prevention information efforts, ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of their communication and education efforts. The information collected will be used to improve communication, products, and services that support key office activities including: Healthy People, Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, healthfinder.gov, and increasing health care quality and patient safety. ODPHP communicates through its Web sites (www.healthfinder.gov, www.HealthyPeople.gov, www.health.gov) and through other channels including social media, print materials, interactive training modules, and reports. Data collection will be qualitative and quantitative and may include in-depth interviews, focus groups, web-based surveys, omnibus surveys, card sorting, and various forms of usability testing of materials and interactive tools to assess the public’s understanding of disease prevention and health promotion content, responses to prototype materials, and barriers to effective use.

The program is requesting a 3-year clearance.

Likely Respondents: Respondents are likely to be either consumers or health professionals.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Data collection task | Instrument/form name | Number of respondents | Number responses/respondent | Average burden/response (in hours) | Total response burden (in hours) |
|---------------------------|----------------------|-----------------------|-----------------------------|------------------------------------|----------------------------------|
| In-depth interviews | Screeners | 1,500 | 1 | 10/60 | 250 |
| | Interviews | 500 | 1 | 1.00 | 500 |
| Focus groups | Screeners | 2,925 | 1 | 10/60 | 487.5 |