References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. 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. Andrews, J.C. (2011). ''Warnings and Disclosures.'' In *Communicating Risks and Benefits: An Evidence-Based User's Guide.* Fischhoff, B., N.T. Brewer, and J.S. Downs, (Eds). FDA: Silver Spring, MD, pp. 149–161.
2. Russo France, K. and P. Fitzgerald Bone (2005). ''Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels.'' *Journal of Consumer Affairs,* 39(1), 27–51.
3. Mason, M.J. and D.L. Scammon (2011). ''Unintended Consequences of Health Supplement Information Regulations: The Importance of Recognizing Consumer Motivations.'' *Journal of Consumer Affairs,* 45(2), 201–223.
4. Betts, K.R., K.J. Aikin, V. Boudewyns, M. Johnson, et al. (2017). ''Physician Response to Contextualized Price-Comparison Claims in Prescription Drug Advertising.'' *Journal of Communication in Healthcare,* 10(3), 195–204.
5. Betts, K.R., V. Boudewyns, K.J. Aikin, C. Squire, et al. (2018). ''Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements.'' *Research in Social and Administrative Pharmacy,* 14(10), 951–963.
6. Sullivan, H.W., A.C. O'Donoghue, K.T. David, and N.J. Patel (2018). ''Disclosing Accelerated Approval on Direct-To-Consumer Prescription Drug websites.'' *Pharmacoepidemiology and Drug Safety,* 27(11), 1277–1280.

Dated: June 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14514 Filed 7–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1538]

Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next PDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by August 17, 2020. Stakeholder meetings will be held monthly. It is anticipated that they will commence in September 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to *PDUFAReauthorization@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of PDUFA. PDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of human drugs. The authorization for the current program (PDUFA VI) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process.

Section 736B(f)(1) of the FD&C Act (21 U.S.C. 379h–2(f)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next PDUFA program. FDA will initiate the reauthorization process by holding a public meeting on July 23, 2020, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in September 2020.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, healthcare professional associations, as well as scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on PDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all stakeholder consultation discussions while FDA

negotiates with the regulated industry. If a stakeholder decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly stakeholder consultation meetings after notifying FDA of this intention (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 736B(f)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding PDUFA reauthorization, please provide notification by email to *PDUFAReauthorization@fda.hhs.gov* by August 17, 2020. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: July 1. 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14585 Filed 7–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5973]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by August 6, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations

OMB Control Number 0910–NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

Prescription opioids play a significant role in the opioid misuse and abuse epidemic in the United States. Opioid analgesics with properties designed to deter abuse, commonly known as abuse deterrent formulations (ADFs), may play a role in helping to curb this epidemic. Currently available ADFs have been demonstrated to deter some forms of abuse (injection, snorting, or, in some cases, chewing and swallowing). FDA's own research and other evidence suggests considerable variability in health care providers' (HCPs) knowledge of and attitudes toward prescription opioid products and practices (Ref. 1), including understanding of ADFs. ADF prescription practices may present opportunities for HCPs to reduce opioid abuse. Conducting a comprehensive evaluation of opioid prescribers' knowledge, attitudes, perceptions, experiences, and behaviors related to ADFs will help to inform FDA's approaches to ADFs.

Given the significance and far-reaching nature of the opioid crisis, along with FDA concerns about potential misunderstanding among HCPs about ADF terminology and capabilities, FDA determined that systematic research was necessary to provide the detailed and comprehensive evidence on which to base the Agency's ADF-related policy, regulatory, and communication decisions, including potential alternative language that may be necessary to describe and explain these products. This work aligns with Priority 1 of the FDA's Strategic Policy Roadmap (*https://www.fda.gov/about-fda/reports/healthy-innovation-safer-families-fdas-2018-strategic-policy-roadmap*), and the Department of Health and Human Services (HHS) and the Administration have similarly placed high priorities on addressing the epidemic of misuse and abuse of opioid drugs harming U.S. families.

The study's purpose is to explore and assess the ADF-related knowledge, attitudes, and behaviors among opioid prescribers (physicians, nurse practitioners and physician assistants) and dispensers/pharmacists, including the related terms addiction and abuse deterrence, and to explore possible alternative language for describing these products. Phase 1 consisted of focus groups (OMB approval under control number 0910–0695). The research described in this notice represents Phases 2 and 3 of the overall project.

Phase 2 will consist of a survey based on the Phase 1 focus group findings related to: (1) Health care provider understanding of addiction, abuse, and abuse deterrent formulations; (2) attitudes toward, perceptions about, and experiences with abuse-deterrent opioid analgesics and abuse deterrence, including prescribing decisions and practices, potential barriers to using ADFs, the quality and understandability of the ADF nomenclature, and the underlying reasons for these perceptions; and (3) HCPs' ideas for minimizing confusion about ADFs, the kinds of ADF training needed, and suggested language/terms they believe would best convey the concept of abuse deterrence to HCPs. The objective of the survey will be to determine the prevalence of HCP knowledge, attitudes, behaviors, and perceptions identified through the qualitative discussion occurring in the Phase 1 focus groups and to uncover any subgroup differences among opioid prescribers and dispensers. We will conduct one pretest, averaging not longer than 20 minutes, to pilot the main survey