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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patroula Smpokou, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5328, Silver Spring, MD 20993, 240–402–9651; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Mucopolysaccharidosis Type III (Sanfilippo Syndrome): Developing Drugs for Treatment.'' This draft guidance provides the Agency's recommendations regarding the structure of clinical development programs for investigational drugs intended to treat mucopolysaccharidosis type III. This draft guidance is intended to facilitate greater consistency in approaches among development programs and to ensure that sponsors receive clear and specific guidance to foster greater efficiency of drug development in this rare disease. The draft guidance describes specific considerations relating to eligibility criteria and trial design and discusses the Agency's current recommendations for efficacy endpoints to support approval of drugs for mucopolysaccharidosis type III.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Mucopolysaccharidosis Type III (Sanfilippo Syndrome): Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 (Investigational New Drug Application) have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 314 (Applications for FDA Approval to Market a New Drug) have been approved under OMB control number 0910–0001, including 21 CFR 312.30, 314.50(d)(5), and 314.126(b)(6).

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: January 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02220 Filed 2–4–20; 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; Proposed Collection; 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 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 research entitled ''Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations.'' This research consists of a survey examining the health care providers' current perceptions, understanding, and behaviors related to opioid analgesic abuse deterrent formulations (ADFs) and a study exploring the effectiveness of different terminology and descriptions for these products.

DATES: Submit either electronic or written comments on the collection of information by April 6, 2020.

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 April 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 6, 2020. 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–2019–N–5973 for ''Agency Information on Collection Activities; Proposed Collection; Comment Request; Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations.'' 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 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 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.govinfo.gov/content/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: 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.*

For copies of the questionnaire contact: Office of Communications (OCOMM) Research Team, *CDEROCOMMResearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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 White House 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 consists 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 procedures among the target HCP populations. The main survey will also average 20 minutes.

Phase 3 will build on findings from the Phase 1 focus groups and Phase 2 survey and will consist of an experimental study examining variations in descriptive terminology for abuse deterrent formulation products. We will conduct two pretests, each averaging not longer than 20 minutes, to test the experimental manipulations and pilot the main study procedures. The main study procedure will also average 20 minutes in length. Participants will be randomly assigned to read one description of an abuse deterrent formulation prescription drug product and then complete a questionnaire that assesses their comprehension and perceptions of the information, including terminology. We will test up to four variations in wording, including the description of ADF included in FDA's guidance ''Abuse Deterrent Opioids—Evaluation and Labeling'' (Ref. 2).

For all phases of this research, we will recruit adult health care professional volunteers 18 years of age or older. We will exclude individuals who work for HHS or work in the health care, marketing, or pharmaceutical industries. The sample will consist of 10 percent pharmacists, at least half of whom dispense ADF opioids. The other 90 percent will be prescribers who, at the time they are recruited, spend at least 50 percent of their time seeing patients and who have prescribed opioids to at least five different patients in the last 30 days, with at least half of the opioids they prescribe being for chronic non-cancer pain. The prescriber sample will be segmented to include 70 percent primary care providers (*i.e.,* those practicing in family practice, or internal or general medicine) and 30 percent a mix of specialists practicing in a variety of fields such as rheumatology, neurology, anesthesiology, pain management, emergency medicine, surgery, orthopedics, and physical medicine and rehabilitation. In each of these groups, 60 to 70 percent will consist of physicians, 15 percent nurse practitioners, and 15 percent physician assistants. A minimum of 30 percent must have experience prescribing an ADF opioid.

We will use soft quotas to ensure that our sample includes a diversity of participants, including related to age, race/ethnicity, gender, years and location of practice, and opioid prescribing levels. We will also exclude pretest participants from the main studies, and participants will not be able to participate in more than one phase of the project. With the sample sizes described below, we will have sufficient power to detect primarily small-sized effects for Phases 2 and 3.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2] [4]

Activity	Number of respondents [3]	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Phase 2					
Pretest screener	470	1	470	0.17 (10 minutes)	79.90
Pretest	235	1	235	0.33 (20 minutes)	77.55
Survey screener	2,120	1	2,120	0.17 (10 minutes)	360.40
Survey	1,060	1	1,060	0.33 (20 minutes)	349.80
Phase 3					
Pretests screener	732	1	732	0.17 (10 minutes)	124.44
Pretests	366	1	366	0.33 (20 minutes)	120.78
Main study screener	2,120	1	2,120	0.17 (10 minutes)	360.40
Main study	1,060	1	1,060	0.33 (20 minutes)	349.80
Total					1,823.07

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Includes total burden for project phases 2 and 3.
[3] Includes 10 percent overage.

[4] With online surveys, several participants may be in the process of completing the survey at the time that the total target sample is reached. Those participants will be allowed to complete the survey, which can result in the number of valid completes exceeding the target number. With this in mind, we have included an additional 10 percent over our target number of valid completes to account for some overage.

II. References

The following references marked with an asterisk (*) are on display at 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; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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. Hwang, C.S., L.W. Turner, S.P. Kruszewski, et al. ''Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion.'' *The Clinical Journal of Pain, 32*(4), 279–284, 2016.

2. * FDA (2015). ''Abuse Deterrent Opioids—Evaluation and Labeling: Guidance for Industry.'' Available from *https://www.fda.gov/downloads/Drugs/Guidances/UCM334743.pdf.*

Dated: January 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02236 Filed 2–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0418]

Nonprescription Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Nonprescription Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on March 11, 2020, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security information, please refer to *https://www.fda.gov/about-fda/white-oak-campus-information/public-meetings-fda-white-oak-campus.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–0418. The docket will close on March 10, 2020. Submit either electronic or written comments on this public meeting by March 10, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 10, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 10, 2020. 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.

Comments received on or before March 3, 2020, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information and consider any comments submitted to the docket, as appropriate.

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):* 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–2020–N–0418 for ''Nonprescription Drugs 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