and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24233 Filed 11–5–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4763]

Agency Information Collection Activities; Proposed Collection; Comment Request; Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

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 ''Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion.''

DATES: Submit either electronic or written comments on the collection of information by January 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 January 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 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–4763 for ''Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion.'' 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.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: 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 Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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.

Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

OMB Control Number 0910–New

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.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform all three topic areas.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a direct-to-consumer survey conducted in 1999.

The present research involves assessment of how consumers and primary care physicians (PCPs) interpret terms and phrases commonly used in prescription drug promotion. This includes both what these terms and phrases mean to each population (*e.g.,* definitions) and what these terms and phrases imply (*e.g.,* about efficacy and safety). Some examples of interest include: ''natural'' or ''naturally-occurring,'' and ''targeted'' or ''targeted therapy.'' The full list for assessment will include approximately 30 terms and phrases for each population. To accommodate such a large number, presented terms and phrases will be accompanied by only limited context (terms within sentences and phrases within paragraphs, as opposed to full promotional materials). Understanding the most prevalent interpretations of these terms and phrases can help OPDP determine the impact of specific language in prescription drug promotion. For example, certain terms and phrases, when used without additional contextual information, might overstate the efficacy or minimize the risk of a product. Additionally, from a health literacy perspective, it is helpful to ascertain general understanding of such terms and phrases as this may aid in the development of best practices around communicating these concepts.

We plan to conduct this research in two phases. First, we will conduct formative semi-structured interviews with 30 members of each population (general population consumers and PCPs). Second, we will conduct nationally representative, probability-based surveys of more than 1,000 members of each population on the same topic.

Phase 1: Semi-Structured Interviews. In Phase 1 of the research, semi-structured interviews will be conducted by web conferencing using the itracks platform, an online and mobile market research service provider. This approach allows for the participant and interviewer to see each other and includes a whiteboard feature that can be used to show the terms, statements, or passages for participants to read and follow along as the interviewer reads them aloud. This may be helpful in cases where the statements or passages are long, which may make them difficult to understand when read aloud. In addition, the written information may be helpful as a reference as the discussion progresses.

Participation is estimated to take 1 hour. Participants will be recruited by email through itracks and its partner panels. All participants will be 18 years of age or older and must not have participated in a focus group or interview during the previous 3 months. Additionally, for the consumer sample, we will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. For the PCP sample, we will exclude individuals who spend less than 50 percent of their time on patient care. Department of Health and Human Services employees will be excluded from both respondent groups. We will start data collection with a soft launch of three interviews per segment (10 percent) to ensure that all processes are working well. Although we do not intend on making major changes to the interview guides as a result of these soft launch interviews, they will provide an opportunity to make minor changes (*e.g.,* adding interviewer notes). Measurement for this phase will consist of a thematic analysis using a matrix approach to identify themes and mental models common across participants.

Phase 2: Nationally Representative Surveys. In Phase 2 of the research, primarily closed-ended survey questions will be administered to each population. The closed-ended survey

format will allow the team to quantify the frequency or prevalence of certain interpretations or meanings among a nationally representative sample of the general U.S. consumer and physician populations. Final questions and response options will be informed by key interpretations discovered during the Phase 1 interviews. For the consumer survey, we will use a probability sample selected from an address-based sampling frame and conduct the survey using a web-based platform. For the PCP survey, we will obtain a probability sample from the American Medical Association Masterfile and will conduct the survey via mail. For each population, we chose the sampling frame and survey mode that has been shown to produce the highest quality results for that population with respect to coverage, response rates, and nonresponse bias. The same exclusion criteria as specified for Phase 1 will be maintained for Phase 2. Participation is estimated at 20 minutes.

We also plan to embed an experiment in the PCP mail survey. Research has shown that including a pen in the survey package can help to increase response rates and time to response, even potentially reducing the number of reminders required (Refs. 1 and 2). However, the shipping of pens can be costly and often pens are damaged in the mail (*e.g.,* ink can leak, etc.). To determine whether another token incentive might be as effective at increasing response rates, we will randomize half of the sample to receive a pen and half to receive a packet of sticky notes or other token incentive. We will compare response rates between the two groups to help inform methods for future studies.

We set our sample requirements to a 95 percent confidence interval and a 3 percent margin of error assuming an underlying proportion of 0.50 in the population (which is the most conservative estimate and overestimates the sample size relative to alternate proportions). These parameters are commonly used in quantitative survey research (Refs. 3 to 6) and offer balance between precision and cost. Thus, assuming a total U.S. population of roughly 250 million adults aged 18 or older (Ref. 7), we estimate the number of completed surveys to be 1,067 for the general population survey. Assuming a total population of 209,000 PCPs (Ref. 8), with the same 95 percent confidence interval and ±3 percent margin of error, we estimate the number of completes for the provider survey to be 1,062. These sample sizes would also allow us to detect a mean difference between ±0.15 and 0.30 points (Ref. 6).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Hours per response	Total hours
General Population					
Phase 1: Screener completes (assumes 35% eligible).	85	1	85	0.08 (5 minutes)	7
Phase 1: Number of completes	30	1	30	1	30
Phase 2: Screener completes (assumes 90% eligible).	1,185	1	1,185	0.08 (5 minutes)	95
Phase 2: Number of completes	1,067	1	1,067 + 10% [2] = 1,174	0.34 (20 minutes)	399
PCP Population					
Phase 1: Screener completes (assumes 30% eligible).	104	1	104	0.08 (5 minutes)	8
Phase 1: Number of completes	30	1	30	1	30
Phase 2: Screener completes (assumes 90% eligible).	1,180	1	1,180	0.08 (5 minutes)	94
Phase 2: Number of completes	1,062	1	1,062 + 10% [2] = 1,168	0.34 (20 minutes)	397
Total					1,060

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for both samples in the study.

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. Bell, K., L. Clark, C. Fairhurst, et al, ''Enclosing A Pen Reduced Time to Response to Questionnaire Mailings.'' *Journal of Clinical Epidemiology,* 74:144–150, 2016.
2. Sharp, L., C. Cochran, S.C. Cotton, et al., ''Enclosing a Pen with a Postal Questionnaire Can Significantly Increase the Response Rate.'' *Journal of Clinical Epidemiology,* 59:747–754, 2006.
3. Bartlett, J.E., J.W. Kotrlik, and C.C. Higgins, ''Organizational Research: Determining Appropriate Sample Size in Survey Research.'' *Information Technology, Learning, and Performance Journal,* 19:43–50, 2001.
4. Cochran, W.G. (1997) *Sampling Techniques* (3rd ed.). New York: John Wiley & Sons.
5. Dillman, D.A., J.D. Smyth, and L.M. Christian. (2014) *internet, Phone, Mail, and Mixed-mode Surveys: The Tailored Design Method* (4th Ed.). Hoboken, NJ: John Wiley & Sons, Inc.
6. Krejcie, R.V. and D.W. Morgan, ''Determining Sample Size for Research Activities.'' *Educational and Psychological Measurement,* 30: 607–610, 1970.
7. *U.S. Census Bureau. (2017) ''National Population by Characteristics: 2010–2017.'' (Available at: *https://www.census.gov.*)
8. *Agency for Healthcare Research and Quality. (2011) ''The Number of Practicing Primary Care Physicians in the United States.'' Retrieved from *http://www.ahrq.gov/research/findings/*

factsheets/primary/pcwork1/index.html.

Dated: October 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24229 Filed 11–5–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice; correction.

SUMMARY: The original **Federal Register** Notice announcing the December 2019 Advisory Commission on Childhood Vaccines (ACCV) meeting indicated that this meeting would be held December 5–6, 2019. This meeting is not being conducted over two days, and instead will only take place only on December 5, 2019.

The ACCV will hold a public meeting on December 5, 2019, at 10:00 a.m. Eastern Time via Adobe Connect and telephone conference. This will not be an in-person meeting. The public can join the meeting by:

1. (Audio Portion) Calling the conference phone number: 800–988–0218 and providing the following information:

Leader Name: Ms. Tamara Overby
Password: 9302948

(Visual Portion) Connecting to the ACCV Adobe Connect Meeting using the following URL: *https://hrsa.connectsolutions.com/accv/.* Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview using URL: *http://www.adobe.com/go/connectpro_overview.*

Information about the ACCV and the agenda for this public meeting can be obtained at the following website: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.*

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Program Analyst, Division of Injury Compensation Programs (DICP), HRSA, in one of three ways: (1) Send a request to the following address: Annie Herzog, Program Analyst, DICP, HRSA, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857; (2) call (301) 443–6593; or (3) send an email to *aherzog@hrsa.gov.* Meeting times could change. For the latest information regarding the meeting, including start time, please check the ACCV website at: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.*

This meeting will only take place on December 5, 2019 and is not being conducted over two days (December 5–6, 2019) as stated previously in the **Federal Register** *(FR Doc. 2019–00439 Filed 1–30–19).*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–24166 Filed 11–5–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, through the use of automated collection techniques or other forms of information technology.

Proposed Project: Protection and Advocacy for Individuals With Mental Illness (PAIMI) Annual Program Performance Report (OMB No. 0930–0169)—Extension

The Protection and Advocacy for Individuals with Mental Illness (PAIMI) Act at 42 U.S.C. 10801 *et seq.,* authorized funds to the same protection and advocacy (P&A) systems created under the Developmental Disabilities Assistance and Bill of Rights Act of 1975, known as the DD Act (as amended in 2000, 42 U.S.C. 15001 *et seq.*]. The DD Act supports the Protection and Advocacy for Developmental Disabilities (PADD) Program administered by the Administration on Intellectual and Developmental Disabilities (AIDD) within the Administration on Community Living. AIDD is the lead federal P&A agency. The PAIMI Program supports the same governor-designated P&A systems established under the DD Act by providing legal-based individual and systemic advocacy services to individuals with significant (severe) mental illness (adults) and significant (severe) emotional impairment (children/youth) who are at risk for abuse, neglect and other rights violations while residing in a care or treatment facility.

In 2000, the PAIMI Act amendments created a 57th P&A system—the American Indian Consortium (the Navajo and Hopi Tribes in the Four Corners region of the Southwest). The Act, at 42 U.S.C. 10804(d), states that a P&A system may use its allotment to provide representation to individuals with mental illness, as defined by section 42 U.S.C. 10802 (4)(B)(iii) residing in the community, including their own home, *only,* if the total allotment under this title for any fiscal year is $30 million or more, *and* in such cases an eligible P&A system *must* give priority to representing PAIMI-eligible individuals, as defined by 42 U.S.C. 10802(4)(A) and (B)(i).

The Children's Health Act of 2000 (CHA) also referenced the state P&A system authority to obtain information on incidents of seclusion, restraint and related deaths [see, CHA, Part H at 42 U.S.C. 290ii–1]. PAIMI Program formula grants awarded by SAMHSA go directly to each of the 57 governor-designated P&A systems. These systems are located in each of the 50 states, the District of Columbia, the American Indian Consortium, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.