Act, that the charter for the of the National Advisory Committee on the Sex Trafficking of Children and Youth in the United States (Committee) was renewed on January 18, 2019. The renewal is available at *https://www.acf.hhs.gov/otip/resource/2019naccharter.*

Notice is also given that a meeting of the National Advisory Committee on the Sex Trafficking of Children and Youth in the United States (Committee) will be held on May 28, 2019. The purpose of the meeting is for the Committee to discuss its work on its interim report on recommended best practices for States to follow in combating the sex trafficking of children and youth based on multidisciplinary research and promising, evidence-based models and programs. The members will remain in Phoenix on May 29 to conduct subcommittee meetings and a fact finding site visit.

DATES: The meeting will be held on May 28, 2019. The members will remain in Phoenix on May 29 to conduct subcommittee meetings and a fact finding site visit.

ADDRESSES: The meeting will be held in Phoenix, Arizona at the invitation of Governor Ducey. Space is limited. Identification will be required at the entrance of the facility (*e.g.,* passport, state ID, or federal ID).

To attend the meeting virtually, please register for this event online: *https://www.acf.hhs.gov/otip/resource/nacagenda0519.*

FOR FURTHER INFORMATION CONTACT: Katherine Chon (Designated Federal Officer) at *EndTrafficking@acf.hhs.gov* or (202) 205–4554 or 330 C Street SW, Washington, DC, 20201. Additional information is available at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

SUPPLEMENTARY INFORMATION: The formation and operation of the Committee are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of federal advisory committees.

Purpose of the Committee: The purpose of the Committee is to advise the Secretary and the Attorney General on practical and general policies concerning improvements to the nation's response to the sex trafficking of children and youth in the United States. HHS established the Committee pursuant to Section 121 of the Preventing Sex Trafficking and Strengthening Families Act of 2014 (Pub. L. 113–183).

Tentative Agenda: The agenda can be found at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.* The Committee requests public comments in response to their first outline of recommendations available at *https://www.acf.hhs.gov/otip/resource/nacprelim.*

To submit written statements or RSVP to attend in-person or make verbal statements, email *Ava.Donald@acf.hhs.gov* by May 10, 2019. Please include your name, organization, and phone number. More details on these options are below.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public. Seating is on a first to arrive basis. Security screening and a photo ID are required. Space and parking is limited. The building is fully accessible to individuals with disabilities.

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public may submit written statements in response to the stated agenda of the meeting or to the committee's mission in general. Organizations with recommendations on best practices are encouraged to submit their comments or resources (hyperlinks preferred). Written comments or statements received after April 10, 2019 may not be provided to the Committee until its next meeting.

Verbal Statements: Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public are invited to provide verbal statements during the Committee meeting only at the time and manner described in the agenda. The request to speak should include a brief statement of the subject matter to be addressed and should be relevant to the stated agenda of the meeting or the Committee's mission in general.

Minutes: The minutes of this meeting will be available for public review and copying within 90 days at: *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

Dated: March 4, 2019.

Lynn A. Johnson,

Assistant Secretary for Children and Families.

[FR Doc. 2019–04403 Filed 3–8–19; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0215]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Healthcare Professional Survey of Professional Prescription Drug Promotion

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.

DATES: Fax written comments on the collection of information by April 10, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title, ''Healthcare Professional Survey of Professional Prescription Drug Promotion.'' 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.

Healthcare Professional Survey of Professional Prescription Drug Promotion

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.

The FD&C Act prohibits the dissemination of false or misleading information about medications in consumer-directed and professional prescription drug promotion. As part of its Federal mandate, FDA regulates whether advertising of prescription drug products is truthful, balanced, and accurately communicated (see 21 U.S.C. 352(n)). FDA's regulatory policies are aligned with the principles of free speech and due process in the U.S. Constitution. To inform current and future policies, and to seek to enhance audience comprehension, the Office of Prescription Drug Promotion conducts research focusing on (1) advertising features including content and format, (2) target populations, and (3) research quality. This proposed research focuses on healthcare professionals (HCPs). In 2002 (Ref. 1) and again in 2013 (Refs. 2 and 3), FDA surveyed HCPs about their attitudes toward direct-to-consumer (DTC) advertising and its role in their relationships with their patients. The 2013 survey included multiple types of HCPs: Primary care physicians and specialists, as well as nurse practitioners and physician assistants. Whereas the focus of both previous FDA surveys was on DTC advertising and promotion, the current study is designed to address issues related to professional prescription drug promotion. The goal is to query a representative sample of HCPs about their opinions of promotional materials and procedures targeted at HCPs, clinical trial design and knowledge, and FDA approval status. We will also take this opportunity to ask HCPs briefly about their knowledge of abuse-deterrent formulations for opioid products.

To educate themselves about prescription drugs, HCPs sometimes rely on professionally directed promotional information (Refs. 4–8). In 2012, pharmaceutical companies spent more than $24 billion on marketing to physicians (Ref. 9). The industry exposes healthcare professionals to promotional materials through a variety of mechanisms, including communication with pharmaceutical representatives, journal ads, prescribing software, presentations at sponsored meetings, and direct mail ads (Ref. 10). Several studies indicate that data presented in promotional materials may not be fully comprehended and may even potentially be misleading due to a variety of causes, such as insufficient information, unsupported claims, or a failure to disclose limitations of the information presented (Refs. 11–15).

Although HCPs are learned intermediaries, like most people, they may rely on heuristics, or rules of thumb, in making decisions and may have cognitive biases in the type of information they attend to at any given time. They may be persuaded by strong statements and may not have the time to ascertain accuracy of such information (Ref. 16).

The proposed survey is designed to provide further insights about how professionally targeted prescription drug promotion might influence healthcare professionals' decision-making processes and practices and how information may be communicated more accurately. It is important to note that FDA does not regulate the practice of medicine. However, as previously mentioned, FDA does regulate prescription drug promotion. This survey is designed to inform FDA of various responses to and impacts of prescription drug promotion.

The general research questions in the survey are as follows:

1. What methods and/or channels are used to disseminate prescription drug promotional information to healthcare professionals/prescribers?

2. How knowledgeable and interested are HCPs in clinical trial data and design and its presence in prescription drug promotion?

3. How familiar are HCPs with the FDA approval of prescription drugs and how does this affect prescribing behavior?

In addition, given the critical problem with opioid abuse and addiction in the United States at this time, we plan to ask several questions about prescription drug promotion of opioid products.

HCPs who fall into one of four categories will be recruited online through WebMD's Medscape subscriber network. We propose to complete 700 primary care physician, 600 specialist, 350 nurse practitioner, and 350 physician assistant surveys. HCPs will be included if they see patients at least 50 percent of the time. Both Doctors of Medicine and Doctors of Osteopathy will be included. Primary care physicians will include those who indicate they work in general, family, or internal medicine. Specialties were chosen based on prevalence in the United States and prescription drug promotional activity. Specialists will include cardiologists, dermatologists, endocrinologists, neurologists, obstetrician/gynecologists, oncologists, ophthalmologists, psychiatrists, rheumatologists, and urologists. The data will be weighted to adjust for differential coverage of select characteristics such as region and respondent age and gender. Pretesting with 25 respondents will take place before the main study to evaluate the procedures and measures used in the main study.

In the **Federal Register** of March 15, 2018 (83 FR 11539), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received. One comment was outside the scope of the research and is not addressed further. The remaining three comments are addressed below. For brevity, some public comments are paraphrased and therefore may not reflect the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: DTC = direct-to-consumer; HCP = healthcare professional; FDA and ''The Agency'' = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

The first public comment had 19 individual comments, to which we have responded.

(Comment 1a) The exact reach of the WebMD Medscape subscriber network among medical professionals is unclear. With this in mind, the study design could introduce bias by self-selecting physicians who do not accurately reflect the broader physician population. For example, they may be more reliant on internet-based information, have seen more web-based pharmaceutical advertisements, and be demographically different than physicians outside the Medscape network.

(Response 1a) It is true that Medscape is not an exhaustive listing of the entire universe of HCPs, but the evidence suggests that coverage is high. Table 1 below documents the number of providers subscribed to WebMD for the four major strata of HCPs included in the study and the estimated population totals. The coverage is particularly good for primary care physicians (over 80 percent), is reasonable for specialists and physicians assistants (between 60 and 70 percent), and not as good for nurse practitioners (about 45 percent).

TABLE 1—ESTIMATED COUNTS AND COVERAGE BY HEALTHCARE PROFESSIONAL GROUP

Healthcare professional group	WebMD [1]	Estimated population total	Estimated coverage %
Primary care physicians (PCPs)	197,980	[2] 242,800	81.5
Specialists (SPs)	465,020	[2] 724,249	64.2
Physicians assistants	62,874	[3] 92,000	68.3
Nurse practitioners	102,552	[4] 220,000	46.6

[1] WebMD estimated counts of Medscape subscribers by HCP group as of July 2017.
[2] American Medical Association (*https://www.mmslists.com/data/countspdf/AMA-SpecialtyByTOPS.pdf*).
[3] Kaiser Family Foundation (*https://www.kff.org/other/state-indicator/total-physician-assistants/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D*).
[4] American Association of Nurse Practitioners (*https://www.aanp.org/all-about-nps/np-fact-sheet*).

The Medscape frame has a smaller frequency of out-of-scope records (retirees, for example, who have not been dropped from the list), and much better contact information (including email addresses), compared to other possible frames. Potential frame competitors, such as the American Medical Association list of providers, have higher coverage of PCPs and SPs, but also many out-of-scope records. Sampling these records would lead to ineligibles in data collection. Considering both coverage and ineligibility rates, Medscape is of better quality than the alternatives. We are planning to calibrate the weights for the sample providers who answer the questionnaire, using the National Ambulatory Medical Care Survey (NAMCS) estimates as benchmarks, based on gender, age, year of graduation, and practice size. Use of these calibrated weights will guarantee that the percentages across provider type, gender, age, year of graduation, and practice size match the NAMCS percentages, which are our best unbiased estimates of the true population percentages. Thus, the under-coverage from the use of the Medscape frame will not lead to significant imbalances in the distribution of these characteristics which could lead to bias. Calibration eliminates bias-producing imbalances for cells defined by the calibration characteristics, but does not eliminate imbalances within these cells. It may be the case that within the provider type-gender-age-graduation year-practice size cells, the Medscape population differs from the universe because of their self-selection into Medscape. This will generate coverage biases of unknown magnitude, but we anticipate that the size of these biases will be small as a component of overall mean-squared-error in this study and will not materially affect the analyses.

(Comment 1b) If specialties are planned to be analyzed individually, the sample size should be at least 50 respondents from each specialty.

(Response 1b) Our analysis plan does not include a separate full-scale analysis for each specialty, though specialty will be included in the analyses as a covariate along with other provider characteristics. Thus, the 50-respondent minimum per specialty is not necessary given the goals of this study.

(Comment 1c) We did not have access to the full screening criteria and have several suggestions for the criteria: a mix of age, practice experience, practice setting, number of patients seen each month, and gender.

(Response 1c) Our screening instrument captures the suggested items, including age, gender, race/ethnicity, practice setting, percent of time seeing patients, and clinical specialty. The survey instrument collects information on the number of patients seen weekly and number of years in practice.

(Comment 1d) Q[uestion]2 currently asks how often physicians visit commercial prescription drug websites. This is a broad question, and we suggest adding followup questions to understand why the physician went to the website (*i.e.,* interested in getting specific product information, patient assistance program information, etc.), what specific information was sought (*i.e.,* promotional information, educational resources, patient support services, prescribing information) and how helpful was the information.

(Response 1d) Prescription drug websites are one of several information sources that are asked about in the survey. The primary goal of our questions about sources of information is to capture the amount of exposure or use of various information sources by HCPs. This may be a good avenue for further research.

(Comment 1e) Responses to Q3 could skew towards more frequent use than the average prescriber since the sample is being recruited from a network of physicians subscribing to a reference website (WebMD Medscape).

(Response 1e) We acknowledge there may be a coverage bias from the use of the WebMD Medscape as a frame, but do not know exactly the magnitudes of bias for particular items. We will document the nature of our frame and the potential implications of that. See response to comment 1a for more details on WebMD sample.

(Comment 1f) Q7a asks respondents to gauge the influence of various information sources on their colleagues' prescribing decisions. Q7b asks about the influence of various information sources on the respondent's prescribing decisions. Influence is subjective and respondent answers to these questions are inherently unreliable. We suggest asking about behavior to help understand influence. If these questions are retained, we suggest reordering the questions.

(Response 1f) We are interested in HCPs' perceptions of relative influence of different information sources. An assessment of the actual influence of these sources through prescribing data is beyond the scope of this project. This is a valuable avenue for future research. Moreover, this question is designed to build on research literature which suggests that HCPs typically rate promotional materials as being more influential on colleagues than on themselves (Refs. 17 and 18). Thus, we ask about the influence of promotional information for both colleagues and the respondent. We will randomize the presentation order of these two questions in the survey.

(Comment 1g) For Q9–Q10, questions and answer choices are overly broad to provide actionable insight. For example, respondents might define ''information about clinical trial designs or clinical trial outcomes'' differently, along with what ''Some'' versus ''Lots'' of information represent. We suggest revising Q9 to ''Do you need more clinical trial design information in order to understand or interpret the clinical

trial data and outcomes presented in promotional material?'' We suggest revising Q10 to ''Do you need more clinical trial outcomes information in order to make sound clinical decisions for your patients?''

(Response 1g) We have made some changes to these questions as a result of cognitive testing. For example, we replaced ''clinical trial design'' with ''clinical trial methodology'' and included examples of what is meant by methodology in parenthesis (*e.g.,* sample, study design). We also changed answer choices to make them more distinct. The choices are now: All information, a moderate amount, a minimal amount, and none.

(Comment 1h) We suggest revising Q14 into two separate questions. One question about the type of training (*e.g.* formal school, continuing medical education, peers) and a separate question on how much training in different aspects of clinical trial design the respondent completed.

(Response 1h) We are using the question about clinical trials training as a covariate to other questions in the survey about clinical trials. Training may influence the amount of clinical trials information HCPs want included in promotions or their level of comfort with clinical trials data. We have added the word ''formal'' to the question to indicate that we are referring to actual training rather than informal discussions with colleagues.

(Comment 1i) Q18 assumes the physician knows whether the drugs prescribed are approved or not approved. We suggest including a selection of ''Do not know.''

(Response 1i) We will add ''Do not know'' as a response option to this question.

(Comment 1j) We have concerns that Q21 fails to define what the Agency means by ''promotion.'' As a result, the question as phrased may suggest that the Agency has broader authority than delegated by Congress or as permitted under the First Amendment to regulate (*i.e.,* ''allow'') protected manufacturer speech that is truthful and non-misleading. We suggest revising Q21 to ask respondents if they value the ability of pharmaceutical companies to provide truthful and non-misleading information about their drugs for indications not approved by FDA.

(Response 1j) Q21 has been deleted.

(Comment 1k) We agree that having an option of ''not sure'' for Q22 is appropriate since many respondents might not be familiar with this approval pathway. However, this could reduce the amount of information this question could assess. We suggest modifying the question to incorporate the definition of accelerated approval and then ask the respondent about his/her comfort level with prescribing. This approach would allow the survey to collect responses from the most respondents possible. We also suggest adding a question prior to Q22 to ask about familiarity or experience with an accelerated approval drug that could be used to assess prior behavior as well as understand how experience with accelerated approval impacts comfort to use.

(Response 1k) We have purposefully not included a definition of accelerated approval, as we are interested in assessing comfort with accelerated approval based on their own understanding of the term. We have added an open-ended question prior to Q22 that asks respondents to describe what an accelerated approval drug is in their own words.

(Comment 1*l*) We recommend modifying the open-ended question (Q23) about scientific exchange and offering respondent components for consideration (*i.e.,* criteria for who is part of exchange of information, description for type of scientific information, description of context of scientific information, and the forum or setting where exchange of information occurs). We also recommend adding question(s) to understand how often respondents engage in settings where scientific exchange typically occurs, such as oral presentations/poster sessions at scientific congresses, review of articles in medical journals, data and clinical trial summaries on clinical trial registries.

(Response 1*l*) The goal of this open-ended question is to assess general awareness/understanding of the term ''scientific exchange.'' In cognitive testing, we found that several HCPs had never heard this term before. Therefore, we need to get a broader sense of general awareness, which may be low, before following up with more specific questions. We have added the option to check ''do not know'' for this question.

(Comment 1m) The open-ended question (Q24) seeking a description of biosimilars will likely result in an extremely wide range of answers with no ability to categorize responses based on the HCP's true knowledge of the term. We suggest framing the question along the lines of how comfortable the HCP is with prescribing biosimilars, therefore, the responses may help correlate knowledge of the term with a greater comfort level in prescribing.

(Response 1m) The goal of this open-ended question is to assess HCP general awareness/knowledge of biosimilars. We have added the option to check ''do not know'' for this question. We also plan to code open-ended responses to determine their level of closeness to the established definition: a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product (42 U.S.C. 262(i)(2)). We have also added a close-ended question prior to Q24 to ask HCPs how comfortable they are prescribing biosimilars.

(Comment 1n) For Q25–26, we recommend including ''don't know'' or ''it depends'' as answer options for these two questions.

(Response 1n) While some cognitive effort is required, we believe the scenarios included in these questions provide sufficient information to allow respondents to make ratings. We also note that during cognitive testing, respondents did not have difficulty answering these questions.

(Comment 1*o*) For Q28, we recommend incorporating a description or definition of ''REMS'' materials.

(Response 1*o*) We have revised the question to spell out the term, Risk Evaluation or Mitigation Strategy (REMS) materials.

(Comment 1p) For Q28a, we recommend a small modification to the question in order to fully capture and connect to the list from the previous question. For example, How often do these materials or *events* mention abuse potential?

(Response 1p) We will revise the question to include ''events.''

(Comment 1q) We suggest adding a followup question to Q27 and Q28 to understand the impact of education/information about opioids on prescribing behaviors. For example, ''Is the number of patients you prescribed opioids for chronic pain in the last 3 months relative to 12 months ago: (1) the same, (2) less or (3) more?''

(Response 1q) We have added this question to the survey.

(Comment 1r) We suggest an additional followup question to Q27 and Q28 to capture how the discussion and information on opioids and abuse potential has changed over recent years, rather than focusing only on the previous 12 months. Asking a retrospective question might capture how the type of information physicians receive has changed as the critical opioid situation has gained more widespread recognition.

(Response 1r) The proposed followup question broadens the scope of the survey in a way that may prevent us from collecting the most relevant data. To capture the element of change in practice over time, as suggested, we

have added a question to ask HCPs whether in the last year the content of promotional materials for opioid products have contained more or less information on abuse potential.

The second public comment responder had 13 comments, to which we have responded.

(Comment 2a) The public comment responder expressed concern that they had difficulty obtaining the proposed survey questionnaire via email, but acknowledged that they were able to obtain it promptly once they contacted the telephone number provided in the 60-day notice. Among other suggestions, the commenter recommended that FDA specify a contact that can directly provide the survey in future notices.

(Response 2a) We appreciate the commenter bringing their experience to our attention. While other commenters that requested the survey did not report that they experienced difficulty promptly obtaining the survey, we take this concern very seriously. Moving forward, in addition to the contact information that has been provided, we will also include the email address of the research team, *DTCResearch@fda.hhs.gov,* in all notices to facilitate obtaining information collection instruments directly from the research team.

(Comment 2b) The proposed HCP survey is duplicative of other information already collected by FDA, such as the previous Healthcare Professional Survey of Prescription Drug Promotion (HCP I survey) and a project referenced on the OPDP website [1] entitled, ''Clinical Trial Data in Professional Prescription Drug Promotion.''

(Response 2b) The HCP I survey was conducted 5 years ago (summer 2013) and focused mainly on HCPs' attitudes toward DTC advertising and its role in their relationship with patients (Refs. 2, 3). The current HCP II survey focuses on promotions directed at healthcare professionals. The existence of some overlapping questions does not constitute in itself a duplicative effort, as there is often a need to compare responses at multiple time points for comprehensive analysis of the issues at hand. Many federally funded national surveys ask the same or similar questions at multiple time points to detect changes and identify trends over time.

We also note the study referenced on the OPDP website is qualitative research with a small non-representative sample, so the design differs considerably from this proposed study. Having multiple studies focusing on differing aspects of a phenomenon, using differing designs and modes, is in accordance with OMB standards to avoid unnecessary duplication of research efforts.

(Comment 2c) The commenter recommends that FDA ask questions about non-opioid analgesic options, medication-assisted treatment for opioid deterrence, and opioid overdose-reversal agents. By asking about this broader range of treatments, the survey would be consistent with the Administration's emphasis on the whole range of medical advances that can help address the opioid crisis.

(Response 2c) We have added a question to address references to these medical advances in prescription drug promotion.

(Comment 2d) We recommend that FDA amend Q1b to ask how closely HCPs read different types of advertisements (*e.g.,* advertisement for new products, or for products related to the HCPs practice).

(Response 2d) We have replaced Q1b with two questions to capture how closely HCPs read the suggested types of advertisements. One will ask about advertisements for new products and one will ask about advertisements for products related to the HCP's practice.

(Comment 2e) We recommend that FDA reword Q2 to avoid the ambiguous term ''commercial.'' Specifically, we recommend FDA revise the question to read as follows: ''How often do you visit product-specific or manufacturer-sponsored ~~commercial~~ prescription drug product websites, such as *lipitor.com*?''

(Response 2e*)* In cognitive testing conducted to develop this survey, the word ''commercial'' was easily understood by respondents and is needed in this question to differentiate it from ''reference'' websites in the subsequent question.

(Comment 2f) We recommend that FDA include a new question under Q2 (*i.e.,* 2a) that is similar to 3b (*i.e.,* that asks how closely the HCP usually reads the prescription drug websites it visits).

(Response 2f) We have added this question.

(Comment 2g) We recommend that FDA clarify whether Q5a applies only to in-person visits from pharmaceutical sales representatives.

(Response 2g*)* During cognitive interviews, respondents had no difficulty understanding that question 5a was asking only about in-person visits. However, we have revised the question to read, ''How often do pharmaceutical representatives bring promotional materials to your practice?'' to clarify that the question refers to in-person visits.

(Comment 2h) We recommend that FDA delete responses 2 (''Lunch for staff'') and 7 (''Personal use item'') from Q5b. It is not clear how these topics relate to FDA's jurisdiction. Other agencies of the Department of Health and Human Services, not FDA, regulate such practices. In addition, these responses do not seem to fall within the stated scope of the survey.

(Response 2h) We have made a minor change to this question by replacing ''lunch for staff'' with ''food and beverages.'' The survey includes questions about the various types of prescription drug promotions and promotional practices that HCPs might be exposed to. To fully understand promotional practices, we also need to know what pharmaceutical representatives provide HCPs during an in-person visit.

(Comment 2i) We recommend that FDA clarify what is meant by the term ''conference'' in Q6.

(Response 2i) We have revised the survey to ask separate questions about ''pharmaceutical dinner meetings'' and ''professional conferences.'' This distinction should make the meaning of professional conference clear.

(Comment 2j) We recommend deleting Q7, as it asks HCPs to speculate about colleagues' perception of promotional materials.

(Response 2j) This question is designed to build on research literature which suggests that HCPs typically rate promotional materials as being more influential on colleagues than on themselves (Refs. 17, 18). Thus, we ask about the influence of promotional information for both colleagues and the respondent. We will randomize the presentation order of these two questions in the survey.

(Comment 2k) We recommend that response 3 for Q8 be amended to identify both the number and type of trials: ''Number and type of trials conducted.''

(Response 2k) Including number and type of trials conducted as one response option will be confusing for respondents and we believe that type of trial is captured by the second response option: ''Study design (*e.g.,* blinded or not, cohort study, length of trial, etc.).''

(Comment 2*l*) We recommend adding the following language to Q18 to ensure consistent use throughout the survey: ''How often do you prescribe a drug for conditions for which it is not approved (*referred to as unapproved use below*)?'' We also recommend amending Q20 to use the term ''unapproved use'' instead of ''off-label use,'' to correspond with

[1] *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm*

question 19 and ensure consistent terminology throughout the survey.

(Response 2*l*) We determined through cognitive testing that HCPs are familiar with and use the term off-label use. The questions have been revised to use ''off-label use'' for all three questions.

(Comment 2m) We recommend deleting Q21, as HCPs perspectives on whether promotion of unapproved uses should be allowed presumes that HCPs know the existing regulatory framework. Moreover, the relevancy of this question is unclear given the stated research goals.

(Response 2m) We have deleted this question.

(Comment 2n) Q31 asks about the respondent's Secondary Specialty. However, it is not clear from the survey if and where Primary Specialty is recorded; we recommend amending the survey to clearly identify the respondent's Primary Specialty.

(Response 2n) Primary specialty is asked in the screener. We have removed the question about ''secondary specialty'' from the survey.

The third public comment responder had one comment, to which we have responded.

(Comment 3a) We suggest adding questions to the survey about how promotional materials and procedures address abuse deterrent formulations (ADF) for opioid products. Specifically, we suggest adding questions related to the following topic areas to assess HCPs' knowledge and understanding of these areas:

- That ADF products have not proven any less addictive than standard non-ADF formulations.
- That the potential for patient harm from dose-dependent misuse of ADF products (*e.g.,* adverse effects resulting from patients taking higher doses of the product than prescribed) or for patients that switch to non-prescribed drugs (*e.g.,* heroin) still remains.
- That potential methods for defeating the ''tamper-proof'' formulation still exist.
- That there are effective ways to protect against accidental ingestion of the drug or theft by others.

(Response 3a) We address the first bullet in question 28c. Various aspects of the remaining bullets are addressed in question 28d. Although the specific points mentioned in this comment are important public health messages, we think these questions are more appropriate for an indepth study of the topic, which is beyond the scope of this project. Please also see our responses to Comments 1r and 2c.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest Study:					
HCP screener	63	1	63	0.08 (5 minutes)	5
Informed Consent	25	1	25	0.08 (5 minutes)	2
HCP Survey	25	1	25	0.33 (20 minutes)	8
Main Study:					
HCP screener	5,037	1	5,037	0.08 (5 minutes)	403
Informed Consent	2,000	1	2,000	0.08 (5 minutes)	160
HCP Survey	2,000	1	2,000	0.33 (20 minutes)	660
Total					1,238

[1] There are no capital costs and maintenance costs associated with this collection of information.

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, OC/Office of Executive Secretariat, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20857 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restrictions. 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.

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Dated: March 5, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04307 Filed 3–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0370]

Agency Information Collection Activities; Proposed Collection; Comment Request; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices; Foreign Letters of Approval

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for firms that intend to export certain unapproved medical devices.

DATES: Submit either electronic or written comments on the collection of information by May 10, 2019.

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 May 10, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 10, 2019. 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–2013–N–0370 for ''Export of Medical Devices; Foreign Letters of Approval.'' 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://*