studies and provides associated technical advice in the areas of study design, sampling, and the collection, management, analysis, and interpretation of injury data; (4) coordinates, manages, maintains and provides tabulations and maps from national surveillance systems and other data sources that contain national, state and local data on injury morbidity, mortality and economic costs; (5) prepares and produces high quality statistical, economic and policy reports and publications material for information presentation and dissemination by NCIPC staff; (6) advises the Office of the Director, NCIPC, in the area of data and systems management and on surveillance and statistical analysis issues relevant to injury program planning and evaluation; and (7) carries out functions listed in numbers (1) to (6) to collaborate with other Divisions/Offices in NCIPC, CDC C/I/Os, PHS agencies, other federal departments and agencies, and private organizations as appropriate.

*Practice Integration and Evaluation Branch (CUHFC).* (1) Monitors and evaluates programs and policies and disseminates findings to promote program accountability and program improvement; (2) promotes an enhanced and sustained infrastructure for a public health approach to injury and violence prevention at state, local and tribal levels; (3) generates and moves practice based knowledge into program practice and research fields; (4) provides expertise in science based public health practice, state-level injury surveillance, and evaluation to state and local health departments; and (5) collaborates with NCIPC OD offices, Division of Community Safety and Trauma Systems, and the Division of Violence Prevention on cross-cutting injury and violence prevention programs, policies, state-level surveillance, and evaluation.

Dated September 25, 2012.

**Sherri A. Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2012–24771 Filed 10–10–12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

**[CFDA Number: 93.612]**

### Announcement of the Award of a Single-Source Grant to the Native American Fatherhood and Families Association (NAFFA) in Mesa, AZ

**AGENCY:** Administration for Native Americans, ACF, HHS.

**ACTION:** Announcement of the award of a single-source grant to Native American Fatherhood and Families Association (NAFFA) in Mesa, AZ, to support activities promoting Responsible Fatherhood in Native American communities.

**SUMMARY:** The Administration for Children and Families (ACF), Administration for Native Americans (ANA) announces the award of a cooperative agreement in the amount of $250,000 to the Native American Fatherhood and Families Association (NAFFA) in Mesa, AZ to conduct a national outreach campaign focused on promoting the importance of fatherhood in Native communities. Included in the national outreach campaign will be a national conference, regional workshops, webinars, and a Native American Responsible Fatherhood Day that will be promoted and implemented throughout Native American communities during the month of June 2013. The award will be made under ANA's program for Social and Economic Development Strategies.

**DATES:** The award will be issued for the time period of September 30, 2012 to September 29, 2013.

**FOR FURTHER INFORMATION CONTACT:** Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, 370 L'Enfant Promenade SW., Washington, DC 20047. Telephone: 877–922–9262; Email: *Carmelia.strickland@acf.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** NAFFA, located in Mesa, Arizona, is a Native non-profit organization whose mission is to strengthen Native Families by responsibly involving fathers in the lives of their children, families, and communities and partnering with mothers to provide happy and safe families.

**Statutory Authority:** This program is authorized under § 803(a) of the Native American Programs Act of 1974 (NAPA), 42 U.S.C. 2991b.

**Lillian A. Sparks,**

*Commissioner, Administration for Native Americans.*

[FR Doc. 2012–25018 Filed 10–10–12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

### Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Administration for Community Living (ACL), the authority vested in the Secretary to execute the competitive grant program under Section 1110 of the Social Security Act, 42 U.S.C. 1310, as appropriate. This authority may be re-delegated.

This delegation does not supersede previous delegations of the authority contained herein, including the delegation to the Administrator, Centers for Medicare & Medicaid Services, ''Delegation of Authority Under Title XI of the Social Security Act, as Amended,'' dated March 4, 2011.

This delegation excludes the authority to issue regulations, to establish advisory committees and councils and appoint their members, and to submit reports to Congress and shall be exercised in accordance with the Department's applicable policies, procedures, and guidelines. I hereby affirm and ratify any actions taken by the Administrator, or his or her subordinates, involving the exercise of these authorities prior to the effective date of this delegation. This delegation is effective upon date of signature.

Dated: October 3, 2012.

**Kathleen Sebelius,**

*Secretary.*

[FR Doc. 2012–25013 Filed 10–10–12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0018]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Healthcare Professional Survey of 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 November 13, 2012.

**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 Prescription Drug Promotion.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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 Prescription Drug Promotion (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 903(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 pharmaceutical industry spends millions of dollars a year promoting their products to American healthcare professionals and to consumers. FDA regulates the promotion of prescription drugs to both professionals and consumers. As such, FDA has an interest in determining the attitudes, perceptions, and opinions of healthcare professionals with prescribing authority regarding such promotion. Direct to consumer (DTC) advertising captures the most public attention, making it an important topic of interest to FDA, but the bulk of industry resources are spent in professional promotion, making this an equally important topic for investigation. The current research is designed to explore prescriber opinions of professional and DTC advertising and promotion as well as other aspects of prescriber experience that relate to the promotion of prescription drugs.

The rise of DTC drug advertising and prescription drug promotion has affected healthcare professionals in a number of ways. First, healthcare professionals regularly encounter patients who have been exposed to DTC ads. Second, healthcare professionals also see and hear such ads directly as mass media consumers themselves. Since clarification of the adequate provision requirement for prescription drug broadcast ads in 1997, FDA has faced numerous questions about the influence of DTC pharmaceutical marketing because such advertising directly engages consumers and potentially affects interactions between patients and their physicians (Refs. 1 and 2). Those questions have grown more urgent with the growth of DTC in recent years (Refs. 3 and 4). In 2002, FDA considered this form of promotion sufficiently important as a force in the physician-patient interaction that they surveyed both patients and physicians regarding their perceptions of DTC (Ref. 5). Now, nearly a decade later, there are critical reasons to return to the field to gather more evidence on the influence of DTC in the examination room and on the relationships between healthcare professionals and patients.

One of the most noteworthy aspects of the current healthcare environment in 2012 is the role now played by various physician extenders. Naylor and Kurtzman (Ref. 6) recently noted that nurses are the single largest group of healthcare professionals in the United States and they argue that nurse practitioners will play an increasingly vital role in primary care delivery. Similarly, physician assistants also bolster the ability of our healthcare system to offer some types of care at lower cost. The aforementioned 2002 FDA study did not include nurse practitioners or physician assistants in the sample; that study focused on general practitioners and specialists in several key areas targeted by DTC. Murray and colleagues (Ref. 7) also conducted a large-scale survey of U.S. physicians regarding their perceptions of DTC, but they also did not include nurse practitioners or physician assistants in their sample. Because DTC likely affects daily interactions between patients and nurse practitioners and physician assistants—similar to the 2002 FDA study that suggested the influence of advertising on physicians' work lives—including these groups in the new sample will further understanding of DTC in the healthcare system.

Another limitation of the 2002 FDA study was the extent to which the results were nationally representative. As FDA has acknowledged, the initial set of results as reported were applicable to survey respondents but were not weighted to reflect national statistics as to the age, sex, and racial composition of the healthcare professional population. Similar to many types of surveys that have struggled in recent decades with declines in cooperation rates (Ref. 8), surveys of healthcare professionals in general often can benefit from weighting to reduce nonresponse bias. The current survey will include weighted responses from respondents that will reflect national demographic patterns.

Over the past decade, researchers have been able to better assess how DTC has unfolded in the United States and determine the questions that warrant further survey work. For example, researchers have worried for a number of years that DTC might produce adverse outcomes, such as clinically inappropriate patient requests for drugs or patient overestimation of the efficacy of advertised medications (Refs. 5, 7, 9, and 10). At the same time, the 2002 FDA survey found that roughly as many physicians thought DTC had a positive effect on their practice as those who thought there had been a negative influence. Moreover, the 2002 FDA survey found that roughly a third of physicians surveyed thought that DTC had essentially no influence on their practice. The question of whether a similar pattern will emerge now, despite the growth of DTC, is a vital one.

In addition, with the proliferation of social media platforms, the emergence of online pharmaceutical marketing, and the evolution of office detailing practices (Refs. 11 and 12), FDA will benefit by knowing more about healthcare professionals' awareness of new and emerging drug promotion sites and practices. The proposed survey will address these issues.

### Design Overview

We propose a nationally representative sample of healthcare professionals that will yield 2,000 responses from 500 general practitioners, 500 specialists, 500 nurse practitioners, and 500 physician assistants. Such a design will help to ensure our ability to discuss not only healthcare professional perceptions generally but also to assess potential

variation between different types of healthcare professionals. The data will be weighted to the national population of physicians, nurse practitioners, and physician assistants who have prescribing authority. We will develop weights to adjust for known unequal selection probabilities, for unequal response rates, and for any remaining deviations between the sample and population distributions. In the final step, we will use poststratification to calibrate the sample distribution to known population distribution to reduce the bias due to frame undercoverage. We believe that poststratification should reduce undercoverage bias to some extent for the same reasons that weighting adjustment reduces nonresponse bias. Population counts for use in poststratification will be obtained from the American Medical Association Master List and Medical Marketing Service lists for nurse practitioners and physician assistants. Available variables on which to weight include: State of practice and specialty for nurse practitioners and physician assistants. For physicians, these variables include: Age, gender, specialty, office based/hospital based; degree (MD or DO) and year of medical school graduation.

All parts of this study will be administered over the Internet. Participants will answer questions about their attitudes about DTC and professional prescription drug promotion, their perceptions of the Bad Ad program, and their usage of new technologies, including social media (for complete questionnaire contact Daniel Gittleson (see **FOR FURTHER INFORMATION CONTACT**). Demographic information will also be collected. The entire procedure is expected to last approximately 20 minutes. This will be a one-time (rather than annual) information collection.

In the **Federal Register** of January 17, 2012 (77 FR 2299), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received five public comment submissions which included over 50 comments embedded. In the following section, we outline the observations and suggestions raised in the comments and provide our responses:

(Comment 1) Two comments recommended surveying pharmacists in addition to the health care professionals described in the notice (i.e., general practitioners, specialists, nurse practitioners, and physician assistants).

(Response) We respectfully acknowledge the large role played by pharmacists in the health care system. However, the purpose of our survey is to query health care professionals with prescribing privileges. One comment noted that pharmacists have some limited prescribing privileges in certain States. This is true; pharmacists have certain privileges in Florida, can prescribe controlled substances under Collaborative Drug Therapy Management agreements in seven States, and with specific advanced training can prescribe within the Veterans Administration system. This contrasts with the nearly universal prescribing privileges of nurse practitioners and physician assistants, with varying levels of physician supervision. To maximize our resources, we propose to maintain our current distribution of health care professionals. Given the variety of prescribing privilege rights among physician extenders in different states, however, we will add a screening question to ensure that our respondents do have prescribing privileges.

(Comment 2) One comment mentioned adding a variety of different types of prescribers to our sample, including dentists, doctors of osteopathy, and podiatrists.

(Response) The comment incorrectly notes that the 2002 survey did not include a variety of prescribers. Contrary to the comment, the 2002 survey did include a range of specialties, reflecting those therapeutic areas with the highest amount of DTC advertising at that time. The current survey will include specialists who practice in therapeutic areas for which DTC advertising is or has recently been active: Dermatologists; endocrinologists; allergists/pulmonologists, psychiatrists (all of whom were sampled in 2002); rheumatologists; cardiologists; ear, nose, and throat doctors; urologists; neurologists; and pain specialists.

(Comment 3) One comment recommended that demographic questions be added to the beginning of the survey to attain adequate representation, instead of occurring at the end.

(Response) The Internet panel from which this data will be collected already contains much of the demographic information we need to ensure that participants represent a balanced stratification of demographic variables. When relevant information is not available from the panel, screening questions will be asked prior to the questionnaire to obtain the desired information. We prefer to keep other demographic variables at the end of the survey to avoid distracting participants with questions about personal information before they have answered substantive survey questions. We also prefer to ask our most important questions first to avoid any respondent fatigue that may occur throughout the survey. We expect that respondents will have an easier time answering questions about themselves; therefore, these questions will be less subject to participant fatigue.

(Comment 4) One comment recommended adding open-ended questions in several locations in the survey.

(Response) We appreciate this suggestion and agree that open-ended questions could provide extra, unprompted information from respondents. However, given the current length of the survey, it is likely that adding many open-ended questions would increase respondent demand and, therefore, result in more respondents quitting before completion. Moreover, the addition of several open-ended questions would increase coding burden without adding a commensurate value to our data. Thus, we do not plan to incorporate additional open-ended questions. If we find data that we would like to pursue further, we can incorporate this approach into future studies.

(Comment 5) One comment recommended that we provide ''don't know'' and ''it depends'' responses for many questions.

(Response) We understand the value of providing such responses for items of a factual nature and for items to which health care professionals might not know the answer (our items fall into the second category). The drawback to providing such response options, however, is that we may lose information by allowing respondents to choose an easy response instead of giving the item some thought. Research by Krosnick et al. (Ref. 13) demonstrated that providing ''no opinion'' options likely results in the loss of data without any corresponding increase in the data quality. Thus, we prefer not to add these options to the survey. We plan to cognitively test the questionnaire before fielding the survey, so we will observe whether participants have particular difficulty with any of the questions.

(Comment 6) A comment recommended interpreting the results of this survey cautiously and in tandem with other ongoing research areas.

(Response) We agree that careful interpretation of the data is crucial. We plan to apply the most rigorous standards of analysis and to interpret the findings based on those analyses alone. When relevant, we will assimilate the findings from this project with other research projects we conduct.

(Comment 7) One comment suggested that Q2 (now Q1) be asked as a screening question.

(Response) We intend to screen based on percentage of time prescribers spend with patients. We do not believe additional screening based on the number of patients seen per week is necessary. We will ask only one of the three options provided in the draft questionnaire. Other comments have recommended asking respondents to recall the last *week* in time, so we will use that question to assess their patient volume.

(Comment 8) One comment recommended asking about ''*health and lifestyle changes*'' as an additional question in Q3 (now Q2).

(Response) We have added this item to the questionnaire.

(Comment 9) This comment recommended eliminating the ''almost always'' option from Q3 (now Q2) because it may confuse respondents in terms of exactly what we are asking.

(Response) We have removed this option and have changed the other responses so now the only responses are ''never,'' ''rarely,'' ''sometimes,'' and ''often.'' We believe this better represents the range of options available to answer this question and will make the question easier to answer.

(Comment 10) One comment recommended that we add a response option to Q4 for in-office programming that occurs in waiting rooms.

(Response) We have deleted this question entirely because of survey time constraints.

(Comment 11) Two comments stated that 1 week is a reasonable amount of time to ask prescribers to recall information in Q5 (now Q3).

(Response) As we have done in the screener and as suggested by these comments, we will use 1 week as the time period.

(Comment 12) This comment recommended that we use a more specific probe in Q6 (now Q4) to gather information on why prescribers feel positively or negatively about patients mentioning advertised prescription drugs.

(Response) We have added a followup probe (Q4a) to address why respondents chose their answer.

(Comment 13) This comment recommended asking prescribers how their patients reference advertisements, for example, whether they specifically mention the drug's name, the condition the drug treats, or some element in the ad such as a butterfly or bee (Q8; now Q5).

(Response) While this is a very interesting question, it is more relevant to marketers of these products and outside the scope of what FDA hopes to accomplish with this survey. Given the number of questions in the survey, we respectfully decline to add this question.

(Comment 14) This comment recommended shortening the timeframe in Q9 (now Q6) from 1 month to 1 week.

(Response) Given the feedback from this and other comments, we agree that 1 week is a reasonable amount of time to reference when answering these questions, and we have adjusted the questionnaire to reflect this change.

(Comment 15) One comment recommended wording changes to Q7.

(Response) Q7 has been deleted because of survey time constraints.

(Comment 16) This comment asked that the nature of the request also be added to Q10 (now Q7).

(Response) Although we agree that asking about the nature of the request would be interesting, additional questions would increase the burden on respondents, and we think that other areas of inquiry are more relevant at this time. Please note that we have altered the response option in this one question, which will yield additional information.

(Comment 17) One comment recommended specifying in Q10 (now Q7) that patients have requested a drug after seeing it advertised.

(Response) The purpose of the question is to assess the prescribing behavior of the prescriber, not the source of the patient's request, so we prefer to keep the question as is.

(Comment 18) This comment recommended a change in the response options in Q10 (now Q7) to further delineate the prescriber's behavior.

(Response) We agree that this is a useful change and have implemented this response format. We have made further changes based on peer review comments.

(Comment 19) Two comments indicated that it may be difficult for health care professionals to answer Q12 (now Q9) as written.

(Response) We agree that it might be difficult for prescribers to reliably assess the feelings and emotions of members of another group. We have changed the emphasis in this question from the patient's expectation to the health care professional's feeling of obligation, thus eliminating the issue over response options in the original item. We have altered the question to put the focus back on what prescribers feel rather than what their patients feel. Please note that we have also altered the response options for this question to make the question easier to answer.

(Comment 20) This comment recommended emphasizing the part of the stem of Q13 and Q14 (now Q11) that states, ''As a result of discussion about advertised prescription drugs.''

(Response) Given the survey length, we have deleted original Q13, but this comment applies to current Q11. We have attempted to emphasize the appropriate part of the stem in this question and will be cognizant of this issue when working with the programmers of the actual survey. We will use bolding techniques and color as necessary to make sure that this part of the question is highlighted.

(Comment 21) One comment questioned the utility of asking prescribers about a variety of behaviors they engage in as a result of a conversation about advertised drugs (Q14; now Q11). Their argument is that the prescriber may respond ''never'' because the subject did not come up, not because they did not want to provide that action.

(Response) We agree that this is a possible interpretation of that response and will be careful to include that in interpretations of the data. Nevertheless, we are interested in obtaining information on the number of times these behaviors occur and believe this is a useful measure.

(Comment 22) One comment recommended changing Q14 (now Q11) from ''provided a brochure for the drug'' to ''provided a *patient education* brochure for the drug.''

(Response) We respectfully decline to add this phrase because not all brochures may be considered patient education brochures, and the addition does not improve or clarify the question.

(Comment 23) One comment recommended making Q15 (now Q12) more specific.

(Response) The purpose of this question is to get a general reaction to DTC advertising. Although we cannot statistically compare the results of this survey to FDA's 2002 physician survey for a number of reasons, we plan to descriptively compare results from the new survey with data obtained in 2002; thus, we prefer to keep the question as is. Although we did not make the question more specific, we have altered the wording slightly to make it clearer.

(Comment 24) This comment recommended the addition of several questions about what happens in the prescriber-patient relationship when patients are exposed to advertised prescription drugs (Q16; now Q13).

(Response) We agree that these are useful questions and have revised the questionnaire accordingly.

(Comment 25) One comment suggested adding a question to Q16 (now Q13) about whether DTC advertising increases the likelihood of conversations that the prescriber would not have otherwise had with his or her patients.

(Response) We have included this suggestion in the revised questionnaire.

(Comment 26) This comment recommended that we add ''the patient requests to be taken off the prescribed medicine'' to Q17 (now Q10).

(Response) We agree this is a useful addition and have added it to the revised questionnaire.

(Comment 27) The comment agreed that the item in Q17 (now Q10) asking about patient recall of aspects of advertised drugs they discuss with their prescribers is valuable, but questions whether the item as worded will yield interpretable results.

(Response) We have revised the question and response options and will pay close attention to this when we conduct cognitive testing with nine participants prior to pretesting the instrument.

(Comment 28) The comment recommended removal of the series of questions in Q17 (now Q10) because many factors may enter into the responses to each question. Specifically, the comment refers to personal characteristics of a patient that may influence these answers.

(Response) We agree that patient characteristics may play a role, but we are interested in the overall responses of prescribers to these questions. Other surveys capture patient characteristics that may influence this question (Ref. 14). We have made minor improvements in the wording of these items based on peer review comments.

(Comment 29) Two comments recommended adding questions to Q18, one of which referred to the effect of DTC advertising on prescription drugs patients are already taking.

(Response) We have added questions on these topics to Q18 (now Q14).

(Comment 30) The comment recommended the addition of several items related to cost to Q21 (now Q17).

(Response) These questions are outside the scope of the current project because FDA does not have authority over the cost of prescription drugs. Given the current length of the survey, we have chosen not to include these recommendations.

(Comment 31) One comment recommended the addition of two questions to the question series for Q22.

(Response) We have included the recommendation in Q14 of the revised questionnaire.

(Comment 32) This comment encouraged FDA to cautiously interpret the results of Q22 (now Q14), which asks whether prescribers believe that DTC advertising caused their patients to think drugs work better than they actually do.

(Response) We agree that all responses should be interpreted cautiously and will take care to avoid overinterpreting beyond the data.

(Comment 33) The comment suggested removing the concept of ''less expensive treatments'' from Q22 (now Q15) about whether prescribers thought DTC advertising caused patients to want advertised drugs over others.

(Response) Although we have heard this complaint frequently in focus groups, we have modified this question so that instead of the comparator in the question being ''less expensive treatments,'' the comparator is ''other recommended treatments.''

(Comment 34) This comment recommended deleting the question about the cost of prescription drugs (Q22).

(Response) We have deleted this question from the questionnaire.

(Comment 35) One comment suggested a change in wording to Q23 (now Q16).

(Response) We have replaced the word ''diagnoses'' with the word ''treatment,'' as suggested by the comment.

(Comment 36) This comment refers to Q23 (now Q18) and the questions following it that inquire about patients bringing coupons to their doctors for specific prescription drugs. Coupons and other incentives are frequently used in DTC promotion. This comment recommended rewording the question to assess whether patients are more likely to ask prescribers for drugs with coupons rather than those without.

(Response) We are unsure how prescribers would know this information because they are likely not current with the range of active advertising campaigns at any given time. We maintain that the currently worded question is a useful measure for assessing prescribers' general opinions about the use of incentives in DTC promotion.

(Comment 37) The comment expressed concern about Q23–25 (now Q18–20) because they believe that without clarification we may miss important nuances such as the possibility that a coupon may initiate a quality conversation about an illness.

(Response) As with all questions in this survey, we will carefully interpret the data, making sure not to draw conclusions not supported by the data. Nevertheless, we believe that if the presentation of a coupon resulted in a good doctor-patient conversation, the respondent would indeed select a positive answer to this question.

(Comment 38) Two comments stated that Q25 (now Q20) repeats Q24 (now Q19) in the questionnaire.

(Response) Q24 (now Q19), asked only of respondents who *have* encountered a patient with a coupon, asks how they *did* feel about that. Q25 (now Q20), asked only of respondents who have *not* encountered a patient with a coupon, asks how they *would* feel about that. Respondents will only see one of these two questions, depending on whether a patient has ever asked them about a prescription drug that has been advertised with a coupon. We like the suggested wording in one comment for Q24 (Q19) and have applied it to both questions.

(Comment 39) The comment suggested modifying Q26 to ask whether prescribers have ever had patients become concerned about their medication after seeing an ad for it.

(Response) We believe this would have been a good introductory question for the former Q26; however, because of survey time constraints, we were forced to limit the number of questions in this area. Based on peer review comments, we replaced these questions with a question that more directly asks whether prescribers have ever had a patient refuse to take or to stop taking their medication for these reasons (now Q21).

(Comment 40) One comment recommended adding a response of ''depends on the condition'' to the question of whether there should be more or less information about medical conditions in DTC advertising (Q27).

(Response) Because of survey time constraints, this question has been deleted.

(Comment 41) One comment recommended changing the order of Q28 and Q29.

(Response) Because of survey time constraints, all questions in this series have been deleted except Q29b (now Q22).

(Comment 42) This comment has taken a subsection of the questions about awareness of the Bad Ad program (Q31–37; now Q23–30) and claimed that FDA is using this forum as a way to inform prescribers about the Bad Ad program.

(Response) Looking at the entire set of questions, it is clear that the goal of this series is to assess whether prescribers have heard about the program and to explore their opinions about it. A description of the Bad Ad program is

provided in current Q24 because we want to ask the subsequent questions of all respondents and can only do so if they know about the program. This survey provides a logical vehicle for assessing opinions about the Bad Ad program. Furthermore, because the Bad Ad program is directly related to prescription drug promotion, we believe it is clearly within the scope of the survey. We recognize, however, that we did not make this clear in the introductory section of the **Federal Register** notice, and we have included additional verbiage to remedy this omission. We note that no other comments expressed concern about these questions.

(Comment 43) One comment recommended wording changes to the followup open-ended item about the Bad Ad program (Q34a; now Q27).

(Response) We agree that the revised wording is preferable and have incorporated it into the questionnaire.

(Comment 44) One comment recommended wording changes to Q36/Q37 (now Q29/Q30).

(Response) We agree that changing the wording of these two questions may make them easier for respondents to understand and have done so in the questionnaire.

(Comment 45) This comment recommended deleting Q38–43 (now Q31–36) regarding social media membership and participation, citing the justification that the survey is about DTC advertising and these questions are irrelevant.

(Response) We reiterate that the purpose of the survey is to obtain opinions and responses from a variety of prescribers regarding prescription drug promotion. This topic encompasses both professional and DTC advertising and labeling and a variety of different media through which this promotion occurs. The Agency has an interest in determining the extent of promotion in emerging technologies such as social media, and various stakeholders have pressed the Agency to produce guidance related to new technologies. This survey provides an opportunity to explore prescribers' use of social media sites in order to assess whether future research is warranted regarding these emerging and potentially promotional venues. We have added language to the introduction section to clarify the scope of the survey.

(Comment 46) One comment recommended that we change the word ''post'' to ''comment'' in Q42/Q43 (now Q35/36).

(Response) We have made this change in these two questions. Please note that we have also added a time period to help respondents answer the questions more easily.

(Comment 47) One comment recommended the addition of Internet search engines to Q44 (now Q37a and 37b).

(Response) We have added search engines as an option for this question. We have also separated the question into two parts based on peer review comments to avoid a cognitively demanding ranking task.

(Comment 48) This comment expressed support for FDA's data collection from health care professionals regarding prescription drug promotion. One general issue raised by this comment was the exclusion and inclusion criteria for prescribers.

(Response) Prescribers must see patients at least 50 percent of the time in a non-hospital or non-inpatient setting. Primary care physicians will include internists, general practitioners, family practitioners, and obstetricians/gynecologists (all of whom were sampled in 2002). We will exclude pediatricians because relatively little DTC advertising is aimed at children or their parents. Specialists will include those who practice in therapeutic areas for which DTC advertising is or has recently been active: Dermatologists; endocrinologists; allergists/pulmonologists; psychiatrists (all of whom were sampled in 2002); rheumatologists; cardiologists; ear, nose, and throat doctors; urologists; neurologists; and pain specialists. Nurse practitioners and physician assistants must have prescribing privileges.

(Comment 49) One comment raised the issue of weighting.

(Response) Although we did not provide details on weighting in the 60-day **Federal Register** notice, we agree and have implemented all suggestions provided by this comment. For example, this comment noted that FDA did not explain at what level results will be reported (i.e., aggregate versus each group as a separate sample). Results will be reported both in aggregate and for each group separately, and weights will be adjusted to produce national-level estimates.

(Comment 50) This comment supported FDA's use of equal-sized samples of four different types of health care professionals (general practitioners, specialists, nurse practitioners, and physician assistants) although it suggests that the artificial nature of equal-sized samples may make it difficult to find population parameters and targets to use for weighting purposes.

(Response) We note that the target population is all health care professionals with prescribing authority in the United States. This is considered the inferential population, which is rarely achieved. The proposed sample will be selected from the ''responding population.'' The final survey weights will be constructed to reduce the coverage error and to compensate for nonresponse error and unequal probability of selection to represent the target population.

(Comment 51) This comment expressed skepticism that sample weighting can adjust or correct for noncoverage that results from inadequacies in sampling frames.

(Response) We agree that frame undercoverage cannot completely eliminate noncoverage bias in an estimator completely but will apply poststratification as the primary method for dealing with this undercoverage (Ref. 15). We believe that poststratification should reduce this bias to some extent for the same reasons that weighting adjustment reduces nonresponse bias. We will consider trimming extreme weights and redistributing them to avoid losses in precision.

(Comment 52) With regard to the questionnaire, this comment recommended adding specific questions about the prescriber's practice, including the size of the practice, whether it is part of a managed care organization, whether it is part of an integrated health system that involves hospitals, and whether the practice has a low- or no-access policy with regard to pharmaceutical sales representatives.

(Response) We agree that these may be relevant variables, and these questions are represented in the demographic section.

(Comment 53) One comment suggested adding a series of questions to assess the market dynamics that may affect prescribing decisions.

(Response) Although these are interesting questions, they are outside the scope of the current project. Many of the suggested questions deal with issues of cost and reimbursement, which FDA does not regulate.

(Comment 54) One comment recommended that we should ask particular questions of nurse practitioners and physician assistants to assess their characteristics.

(Response) We agree with the comment and have several questions in the questionnaire, asked of all respondents, that will address some of these questions. We have added a question to the screener to ensure that all respondents have at least some prescribing authority, and we have added a question to the questionnaire to

delve further into how much authority respondents have. We will also ask all respondents how many prescriptions they write in 1 week.

(Comment 55) One comment suggested reexamining the questionnaire from the Office of Prescription Drug Promotion's online DTC promotion study (Docket No. FDA–2011–N–0230) in light of this survey to explore the possibility of comparing responses on similar questions.

(Response) We appreciate this suggestion and will examine the data from both studies to see if any descriptive comparisons can be made.

Please note that in response to all comments received, whether we have adapted the suggestions or not, we will specifically examine the items mentioned in cognitive testing. During this testing, nine respondents will participate in the survey while explaining why and how they have chosen their answers and which questions they find difficult to respond to or to understand.

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 responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Screener | 3,500 | 1 | 3,500 | 0.03 | 105 |
| Pretest | 25 | 1 | 25 | 0.33 | 8 |
| Main Study | 2,000 | 1 | 2,000 | 0.33 | 660 |
| Total | | | | | 773 |

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

## V. References

The following references have been placed on display in the Division of Dockets Management (FDA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.


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Dated: October 4, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–1025]**

### The Science of Small Clinical Trials; Notice of Course

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA), together with the National Institutes of Health (NIH) Office of Rare Diseases Research, National Center for Advancing Translational Sciences, is announcing a course entitled ''The Science of Small Clinical Trials.'' The course is intended to present an overall framework and provide training in the scientific aspects of designing and analyzing clinical trials based on small study populations. The course will bring together subject experts and stakeholders to identify when such trials should be conducted, along with strategies and trial designs that are conducive to overcoming the challenges they present.

The goal of this course is to engage and educate FDA reviewers, NIH scientists, clinicians, academics and industry representatives with experience in human subject research, seeking to build upon their existing knowledge and to obtain a broader