United States Food and Drug Administration

Healthcare Provider Perception of Boxed Warning Survey

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

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 prescribing information (sometimes referred to as the "PI", "package insert", or "prescription drug labeling") provides a summary of the essential information needed for the safe and effective use of a drug or biological product. A drug's prescribing information may include a boxed warning in addition to other sections of the labeling to highlight important safety information to HCPs. Boxed warnings are an important and frequently used communication tool intended to promote informed treatment decisions and promote safer use behaviors that can mitigate a specific risk in patients who are using a drug.

A review of literature has suggested that the addition or modification of boxed warning information in the postmarket setting (after a drug has been approved) has had varying effects on HCPs' practices regarding prescribing, dosing, and patient monitoring.[1] However, this review and others have identified several gaps in the existing literature, including the limited number of drugs or drug classes studied.[2] Moreover, research conducted to date has primarily focused on behavioral or health outcomes. Few studies have yielded direct evidence into how HCPs receive, process, and use boxed warning information to support their treatment and follow-up decisions.

Research that taps directly into providers' perceptions and decision-making processes is critical to understanding how FDA can achieve its public health goals through effective boxed warning information. HCPs' potential lack of awareness or understanding of these risks, or tendency to minimize the risks, could put patients at unnecessary risk for serious health consequences. On the other hand, interpreting disproportionately high levels of

[1] Dusetzina, S. B., et al., "Impact of FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review," Medical Care, 50(6):466-478, 2012.
[2] Briesacher, B. A., et al., "A Critical Review of Methods to Evaluate the Impact of FDA Regulatory Actions," Pharmacoepidemiology Drug and Safety. 22(9):986-994, 2013.

risk may lead HCPs to avoid prescribing certain drugs that could meaningfully benefit their patients.

The purpose of this project is to conduct web-based surveys with HCPs with prescribing authority to gain understanding of: (1) HCPs' knowledge, beliefs, and attitudes toward boxed warning information; (2) how HCPs' use this information to support their treatment and follow up decisions; and (3) how HCPs communicate boxed warning information to their patients.

2. Purpose and Use of the Information Collection

This study will strengthen FDA's understanding of how HCPs may receive, process, and use boxed warning information and identify HCP's potential information needs with respect to the topics addressed by a product's boxed warning. The research will also provide the opportunity to explore potential differences in perceptions and uses of boxed warning information that may vary based on: (1) the condition being treated; and (2) prescriber specialty (general practitioners and specialist).

This survey will be conducted as part of a mixed methods research approach[3] to explore HCPs' beliefs (or "mental models") about the benefits and risks of a drug that carries a boxed warning and how the drug's boxed warning information may influence their communication with patients, their treatment decisions, and related decisions such as pre-screening for risk factors or monitoring for adverse events. This survey research will build upon preliminary qualitative research FDA has conducted, under OMB control number 0910-0695, with HCPs in this target population through in-depth individual interviews.

This study will inform FDA of the different interpretations HCPs who prescribe medicines may have of boxed warning information. The data collected in this study may inform development of a set of broadly-applicable guiding questions that FDA review teams can consider in their scientific and regulatory assessments about how a boxed warning may support the Agency's risk management goals for an FDA-approved product that is associated with serious risks and on the types of information that may be best conveyed in a potential boxed warning, if determined necessary.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. One hundred percent (100%) of participants will self-administer the survey via a computer of their choice, which will record responses and provide appropriate soft prompts to encourage (but not require) participants to respond to a question that has been left blank. In addition to its use in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time

[3] Morgan, M.G., B. Fischhoff, A. Bostrom, et al., "Risk Communication: A Mental Models Approach," Cambridge University Press, 2002.

basis for each participant, and by keeping the written parts of surveys to less than 20 minutes in both the pretests and main study.

4. Efforts to Identify Duplication and Use of Similar Information

FDA has conducted previous surveys of HCPs' perceptions of FDA-approved prescribing information (OMB Control No. 0910-0479 and OMB Control No. 0910-0730) in 2001 and 2013, Additionally, FDA has one qualitative study in progress about labeling (Physician Interviews on FDA-Approved Labeling, OMB control no. 0910-0695. The proposed survey complements that work by focusing on the specific role of boxed warning information. In 2018, through a cooperative agreement with FDA (7U19FD004971-04), the Duke Margolis Center for Health Policy conducted a literature review (manuscript in submission) and convened an expert workshop to gain a better understanding of the existing research on boxed warning labeling changes and other postmarket safety labeling changes. The literature review and workshop discussion highlighted the need for additional studies, including survey research on HCPs' perceptions.[4] This research is intended to address that need. We know of no current studies that directly explore HCPs' perceptions, beliefs, attitudes and stated influences on decision making with regard to the boxed warning information pertaining to the products included in the two research scenarios in this proposed data collection.

This survey research builds upon preliminary research FDA has conducted, under OMB control number 0910-0695, with HCPs in the same target population through in-depth individual interviews. The qualitative research study provided insights into the type and range of perceptions HCPs have concerning boxed warning information as well as in-depth context for understanding how HCPs may perceive, use, and communicate boxed warning information. The proposed data collection will add unique value by generating estimates of the prevalence of the varying experiences and perceptions in two different prescribing contexts.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small businesses or other small entities. The collection of information involves individuals, not small businesses.

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is one-time only. There are no plans for successive data collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

[4] See 2019. Duke-Margolis Center for Health Policy. "A Framework for Evaluating the Impact of Prescription Drug Postmarketing Safety Labeling Changes, accessed December 11, 2019 at https://healthpolicy.duke.edu/sites/default/files/u31/white_paper_postmarket_safety_labeling_changes_july2019_to_publish.pdf

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of August 8, 2019 (84 FR 38996). FDA received three public comments, the third of which comprised 15 individual comments. Below is a response to each of the commenters' questions. For brevity, some public comments are paraphrased and therefore may not reflect the exact language used by the commenter. The entirety of the public comments was considered even if not fully captured by our paraphrasing in this document.

Comment 1:

The first public comment "agrees with the data collection," but finds the intent of the data collection unclear and expresses concern that "the data will be collecting in the survey will be used adversarially [sic] [against providers]. The commenter described experiences "as a healthcare provider, [battling] daily with both ends of the spectrum," including patients who want a "brand new drug" even though it will likely provide little therapeutic benefit, as well as patients who would benefit from a product but "adamantly refuse based on a [boxed warning]." The commenter further stated that "As a provider, I can present the information I have at hand, but how do I combat new information that is identified specifically, a [boxed warning] post prescribing a new medication?"

Response: FDA appreciates the commenter's experience, which is relevant to the research question that the proposed data collection is intended to inform: how HCPs consider boxed warning information when making treatment decisions and how they communicate boxed warning information to their patients. As described in Section A.2, the intent of the data collection to better understand the range of HCPs' experiences and informational needs regarding boxed warning information.

Comment 2:

The second public comment expressed concern regarding how "[a] voluntary commitment to participating in a professional assessment survey demonstrates some level engagement and awareness [and therefore this] survey will assess an already engaged section of providers, potentially skewing the data."

Response: In accordance with the requirements set forth by institutional review boards and OMB, any research must involve voluntary participation of research participants. We acknowledge there may be a coverage bias from the use of an opt-in web panel as a sample frame (i.e., HCPs who choose to be part of a research panel may differ from HCPs who do not choose to be part of a research panels). As a basic check, in our analysis of the study findings, we will compare the demographic characteristics of the population of survey respondents to the population of U.S. prescribers within the relevant

medical specialties). We will document the nature and limitations of our sampling frame and the potential implications of that on the interpretation of the research findings.

Comment 3:

The third public comment comprised two overarching comments (#1 and #2 below) and 13 additional (#3 - #15) comments on individual items on the questionnaire, to which we have responded below.

Comment 3a: We recommend considering two different "archetypes" for the medical product scenarios to gain insight on different situations. Consideration should be given to a drug/class with a specific risk factors identified in a BW [boxed warning], a drug/class launched with a BW or drug/class with a BW that was established post approval.

Response 3a: We agree with the importance of capturing different archetypes (e.g., characteristics or features) of the medical scenario and of the boxed warning. The identified scenarios, vaginal inserts to treat vulvo-vaginal atrophy (VVA) in post-menopausal women and direct-acting antivirals to treat chronic hepatitis C viral (HCV) infection were identified because they differ along some important characteristics. These characteristics include seriousness of condition, characteristics of the safety concerns, length and nature of the boxed warning information, and length of time since the boxed warning was included.

Comment 3b: We also recommend that the FDA consider additional study designs such as retrospective analysis on prescribing habits. Data could be collected on prescribing habits of medications before and after inclusion of a BW in labeling. This study could be used as a complementary evaluation on the understanding the impact of BW.

Response 3b: We agree that there is value in complementary research approaches using the same scenarios and appreciate the suggestion. We will explore the feasibility of undertaking a related outcomes-focused study looking at prescribing behaviors in future studies.

Comment 3c: In an effort to streamline the questionnaire, [we] recommend considering the removal of [Question 1] and relying on Questions 2-6 to assess the level of experience.

Response 3c: We appreciate feedback suggesting opportunities to streamline the questionnaire, and we have considered appropriate ways to streamline. Q1 elicits a self-assessment of their level of experience treating the scenario condition, which provides very important context for understanding HCPs' perceptions. This concept is distinct from concepts elicited in Q2-6. For example, a self-assessment of experience with a condition may not be associated with the number of patients the HCP currently sees.

Comment 3d: [We] recommend consolidating Q5 and Q6 into a single question… [and] including the drug of interest in the list of options [and] adjusting the [choice] selections

so that they become mutually exclusive. [We] would further recommend screening out physicians from taking remainder of the survey that do not prescribe drugs with BW based on their responses to Q 4-6.

Response 3d: In the questionnaire draft that the commenter reviewed, Q5 asks respondents how often they prescribe the scenario drug and Q6 ask how often they prescribe a number of other types of products that FDA believes providers may be using to treat the condition. In our revised questionnaire (now Q4 and Q5), we keep the two questions as separate, but we have greatly simplified the latter (now Q5) so that it does not elicit prescribing rates, but rather asks respondents to indicate which treatments they have use in a typical month. The elicitation of the frequency ("a few times per month, a few times a year, etc.") is important with respect to the scenario drug. We have modified the response items to be mutually exclusive.

Potential participants are screened based on their experience with treating each of the medical conditions, but not based on their prescribing behavior regarding any the particular product. For the purposes of this research, exclusion due to not prescribing the specific product with the boxed warning is not appropriate, as long as the healthcare provide meets the other criteria. If, for example, a provider chooses categorically not to prescribe a particular product that has a boxed warning, it could be driven in part by his or her perception of the boxed warning information. We are still interested in this prescriber's perception of the benefits and risks of the scenario product.

Comment 3e: There may be a need to differentiate HCPs who initiate vs. those that refill, therefore [we] recommend including a question to ask what % of prescriptions are initiated vs. refill.

Response 3e: We agree that there may be a need to differentiate HCPs who initiate vs. those who only prescribe refills for the scenario drug. Our revised questionnaire (question 4a) now allows differentiation between HCPs who initiate prescriptions versus HCPs who have only prescribed a refill for the scenario drug.

Comment 3f: The description of patient and condition will likely influence the responses and the physicians' consideration of the BW. [We] recommend taking into consideration where the patient is in the treatment journey and where the drug with the BW is in the treatment algorithm. The instructions also imply that this treatment must only be prescribed to females. If the treatment is not limited to females [we] recommend modifying the instructions to be more general neutral.

Response 3f: Where the patient is in the treatment journey and where the treatment is within the treatment algorithm are important concepts. The descriptions of the patient and condition in the revised questionnaire [preceding Q6], identify where the patient is in the journey, and the scenarios were constructed such that the scenario drug with the BW would be considered a commonly-considered treatment option for patients who fit the patient description. One of the scenarios [estrogens to treat VVA] is only applicable to females. The patient description in the HCV scenario questionnaire has been modified to

be gender neutral and to apply to patients in general that the responder sees, not a specific patient.

Comment 3g: [We] recommend asking an additional question after Q7 and 8 to assess reasoning by respondent. This approach can provide an initial indicator of unaided awareness and impact of BW for HCPs. For example, [we] propose: "what are your safety concerns when considering [drug] for patients [open end]."

Response 3g: We agree that eliciting this type of information from respondents is very important. The questionnaire includes a very similar open-ended question [Q11 in the revised questionnaire] to elicit the potential rare but serious side effects that the respondent discusses with patients. In an attempt to minimize respondent burden, we therefore did not add the suggested questions because it would be redundant.

Comment 3h: A physician's response may be dependent on the condition and the contributions of symptoms to the condition. [We] request rational for inclusion of Q9-11 on earlier phase of condition and Q7-8 related to more specific patient and condition descriptions.

Response 3h: In the questionnaire draft that the commenter reviewed included two descriptions. The first description referenced an individual patient with specific characteristics of relevance to the prescribing scenario. With the second description, respondents were asked to think about a broader patient population. Based on the commenter's feedback as well as the results of the cognitive interviewing, we have revised the scenario description to have a single prototypical description of a population of patients of relevance to the prescribing scenario. For example, the scenario used for the VVA questionnaire states: "For the next few questions, we would like you to consider your patients who are postmenopausal women complaining of symptoms such as vaginal itching and discomfort or pain during intercourse. They have previously tried over-the-counter ointments with little success."

Comment 3i: [Regarding Q12] Because risk/benefit considerations will likely be a key factor in deciding whether to prescribe the drug, [we] recommend including risk/benefit as a possible selection. Relevant for inclusion of the selection "This patient's preference about mode of administration" will be depending on the available treatment options for condition selected. [We] recommend adding an option in Q12 of "other (specify)" instead of including 12OTH as a separate question. This approach will enable respondents to rank another option.

Response 3i: We agree that risk/benefit is a critical assessment and factor into HCPs' decisions whether to prescribe a drug, and there are multiple questions in the questionnaire designed to get at this overarching judgment of the respondent. In the questionnaire draft that the commenter reviewed, Q12 (Question 11 in the revised questionnaire) asks respondents to indicate the specific factors that play the most important role when deciding whether or not to prescribe the scenario drug. These factors include separate considerations on both the risks and benefits, such as "patient's

understanding of and comfort with the risks of this medication" and medical history as part of "patient's medical and health context." We did not include a risk/benefit as an option because that would be redundant. We did however, address the commenter's recommendation about Q12OTH (a question to allow for the respondent to identify other factors). Question 11 in the revised questionnaire now includes an option: "other (please specify)" Should the participant feel that we left out risk/benefit assessment as a separate factor, they may input this in the "other (specify)" field.

Comment 3j: [Regarding Q12l] [We] recommend inclusion of a description of the specific risks in BW instead of the proposed option "risks outlined in the boxed warning."

Response 3j: We believe the commenter meant to reference Question 15l. In the questionnaire draft that the commenter reviewed, question 15l asks respondents to indicate specific risks (multiple choice) they discuss with the patient about the product. In the revised question, we modified this to an open-ended question, intentionally designed to elicit spontaneous response about the rare but serious side effects that they discus. Further on in the survey is a specific recall question asking respondents to identify the risks (multiple choice) they recall being discussed in the boxed warning for the specific product.

Comment 3k: [We] recommend moving Question 17 and 18 to the end of the survey, as they seem less important than the following questions 19-22.

Response 3k: In the questionnaire draft that the commenter reviewed, Q17 and Q18 ask respondents to indicate where they typically look or information about the scenario drug or other similar products (medical journals, search engines, etc.). In the revised draft, we have simplified Q17 and Q18 into a single question (now Q15). In light of this comment, we considered other placements for this question. We believe placement of this question is justified as the last question respondents' answer regarding their overall perceptions regarding the scenario drug before they move to focusing their attention on the boxed warning information specifically. We could not determine a better place later in the questionnaire to include this question because it would require the respondent to go back to thinking broadly about information sources.

Comment 3l: Consider moving this general perception question 19 about BW earlier in the survey.

Response 3l: The placement of this question is deliberate. In the questionnaire draft that the commenter reviewed, Q19 ask respondents their opinion of the primary role of a boxed warning (e.g., "to highlight the most serious potential risks of the product; to disclose clinical trial and other product safety testing information."). This questionnaire has been specifically designed to not prime respondents to think about boxed warnings at the start of the questionnaire. We do not disclose that the scenario product carries a boxed warning, nor does it elicit respondents' perception of boxed warnings until they have provided their overall perceptions of the safety and benefit-risk profile of the scenario

product. The intent is to generate and see if concerns about the information relayed in the boxed warning spontaneously arises. The first mention of boxed warning appears immediately before Q19 (now Q16 in the revised questionnaire): "The next questions refers to the boxed warning information on the product labeling for [drug]." Because of this, we have left the question as is in the revised questionnaire.

Comment 3m: Assuming the drug with the BW referenced in the rest of the survey is the BW explicitly shown at this point in the survey, [we] recommend not allowing respondents to go back to "correct" previous answers.

Response 3m: We agree with the commenter's suggestion, and we have set the programming language of the web-based questionnaire to not allow respondents to go back and change their answers.

Comment 3o: Please provide rational for the relevance of asking Question 28_H.

Response 3o: In the questionnaire draft that the commenter reviewed, Q28_H asks respondents provide their estimate of how many prescription drugs they think carry a boxed warning. The question has less relevance compared to other questions in the questionnaire, and it did not add value in the cognitive interviews. Therefore, we excluded the question in the revised questionnaire.

Comment 3p: Assessing "favorability" of a BW is an awkward question. Recommend revising Q29 to an agreement statement. For example, "BW provides important information to me." If Question 29 is revised, then recommend removing Q30.

Response 3p: In the questionnaire draft that the commenter reviewed, Q29 asks the respondent to rate how favorable their opinion is of boxed warnings in general. This question is intended to provide an overall assessment of boxed warnings. The question was not confusing to participants in the cognitive interviews. In addition, another question (Q23 in the revised questionnaire) asks level-of-agreement questions very similar to the type of question the commenter proposes (e.g., "I counsel my patients differently when prescribing a product with a boxed warning.") We did however, exclude the open-ended Q30 in the revised questionnaire, in an effort to streamline the survey and reduce respondent burden.

Comment 3q: [We] recommend adding an option "I'm not sure/I don't know/I'm not familiar" to Questions 2, 3, 4, 7, 8, 12, 14, 15, 23, 24, 25, 28, 29.

Response 3q: We appreciate the commenter's suggestion. We reviewed the survey and added an Unsure/Don't know option where we deemed appropriate: Qs 2, 3, 4, 28, 29. Some questions were removed: 8, 25. Q23 has an "Other (specify)" option where participants can elaborate if they are unable to choose an answer. For certain key questions that elicits respondents' opinions (Qs 7, 12, 14, 15, 24), we did not add Unsure/Don't know in order to encourage them to thoughtfully pick an answer. However, participants can proceed through the questions without providing an answer, if they wish.

9. Explanation of Any Payment or Gift to Respondents

Historically, physicians are one of the most difficult populations to survey, partly because of the demands on their professional time. Consequently, incentives assume an even greater importance with this group. Several studies[5] have discussed the challenges of conducting HCP surveys and have concluded that offering substantial incentives is necessary to attain high response rates. For example, in experiment on the effects of incentives and pre-notifications on response rates in a national web survey of physicians, Dykema et al. (2011) found that the response rate among physicians offered $100 (25.4%) was significantly higher than among the physicians offered $50 (13.4–15.4%), inclusion in a $200 lottery (6.6–8.6%), or no promised incentive (3.0–6.2%).

For both the pretest survey and main survey, PCPs, Internists, NPs, and PAs will be provided an honorarium of $30; OB-Gyn and geriatricians will be provided an honorarium of $40 and hepatologists and infectious disease specialists will be provided an honorarium of $75. These incentives are based on market rates that are offered to physicians and other HCPs for completing surveys. The incentive is an effective method of drawing attention to the study and gaining cooperation for completing the questionnaire. It is not intended as a payment for their time but rather a means for increasing response rates. Recommended rates reflect higher honoraria for specialties, who represent a lower prevalence in the overall HCP population. For example, because there are many more GPs than hepatologists both in the HCP population and the panel (see Table 1), a higher honorarium is necessary to recruit sufficient numbers of hepatologist respondents.

10. Assurance of Confidentiality Provided to Respondents

This ICR does not collect personally identifiable information (PII) or information of a personal nature. FDA Form (FDA Prescriber Survey to Assess Boxed Warnings Perceptions Screenings with Programming Notes) collects respondent ID that is a pre-

[5] Gunn, W.J., and Rhodes, I.N. (1981). Physician response rates to a telephone survey: Effects of monetary incentive level. *Public Opinion Quarterly*, 45(1), 109-115. Deehan, A., Templeton, L., Taylor, C., Drummond, C. and Strang, J. (1997). The effect of cash and other financial inducements on the response rate of general practitioners in a national postal study. *British Journal of General Practice*, 47, 87-90. Dykema, J., Stevenson, J., Day, B., Sellers, S.L., and Bonham, V.L. (2011). Effects of incentives and prenotification on response rates and costs in a national web survey of physicians. *Evaluation & the Health Professions*, 34(4), 434-447. Keating, N.L., Zaslavsky, A.M., Goldstein, J., West, D.W., and Ayanian, J.Z. (2008). Randomized trial of $20 versus $50 incentives to increase physician survey response rates. *Medical Care*, 46(8), 878-881. Tambor, E.S., Chase, G.A., Faden, R.R., Geller, G., Hofinan, K.J., and Holtzman, N.A. (1993). Improving response rates through incentive and follow-up: The effect on a survey of physicians' knowledge of genetics. *American Journal of Public Health*, 83(11), 1599-1603. Ziegenfuss, J.Y., Burmeister, K., James, K.M., Haas, L., Tilburt, J.C., and Beebe, T.J. (2012). Getting physicians to open the survey: Little evidence that an envelope teaser increases response rates. *BMC Medical Research Methodology*, 12(41).

defined identifier, generated and maintained by the web-panel provider and will not have the ability to link the respondent ID to any PII. The other forms that collect information (Questionnaire: Volar and Vaginal Atrophy and Questionnaire: HCV) do not collect PII.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not use name or any other personal identifier to retrieve records from the information collected

In preparing this Supporting Statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

All data will be collected with an assurance that the participants' responses will remain private to the extent allowable by law. The consent form (see Appendix C) contains a statement emphasizing that no one will be able to link a participant's identity to his/her responses and that each participant will only be identified by a respondent ID. Researchers will not tie respondents' personally identifiable information (PII) to their answers, as the panel provider will not be sharing any PII nor will the survey collect any PII. All analyses will be done in the aggregate, and respondent information will not be appended to the data file used.

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The complete list of questions is available in Appendix C.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the annual reporting burden of this collection of information as shown in Table 1. These estimates are based on FDA's and the contractor's experience with previous consumer studies.

Table 1 – Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest Study					

HCP Screener	84	1	84	0.05 (3 minutes)	4
Informed Consent	50	1	50	0.05 (3 minutes)	2
HCP Survey	50	1	50	0.28 (17 minutes)	14
Main Study					
HCP screener	1927	1	1927	0.05 (3 minutes)	96
Informed Consent	1156	1	1156	0.05 (3 minutes)	58
HCP Survey	1156	1	1156	0.28 (17 minutes)	324
Total					498

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

12b. Annualized Cost Burden Estimate

The estimates of annualized hour burden are provided in the table below. See notes below for explanation.

Table 2. --Estimated Annualized Burden Costs			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Practitioners[1]	299	$74.60[2]	$22,305.40
Specialists[3]	199	$114.58[4]	$22,801.42
Total			$45,106.82

1. In accordance with the sample frame (described in Supporting Statement B), General practitioners make up 60% of the research sample and include PCPs, Internists, Family Medicine, Nurse practitioners, and physician assistants.
2. Estimate calculated from the U.S. Bureau of Labor statistics. Because this category "general practitioner" includes a diverse set of healthcare providers across a range of hourly wages, we took an average of the median hourly wage for "Family and General Practitioners" (https://www.bls.gov/oes/current/oes291062.htm), and "Physician Assistants" (https://www.bls.gov/oes/current/oes291071.htm)
3. In accordance with the sample frame (described in Supporting Statement B), General practitioners make up 60% of the research sample and include: OB/GYN, geriatricians, hepatologists, gastroenterologists and infection disease specialists.
4. Estimate calculated from the U.S. Bureau of Labor statistics. Because this category "specialist" includes a diverse set of healthcare providers and the BLS did not provide data on any specialty in this set other than OB/GYN, we used the mean hourly wage for OB/GYN) (https://www.bls.gov/oes/current/oes291064.htm).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is $297,546 ($148,773 per year for 2 years). This includes the costs paid to the contractors to support study design, draw the sample, collect the data, and create and analyze a database of the results. The contract was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not public information. The cost also includes FDA staff time to design and manage the study, to analyze the resultant data, and to draft a report ($65,000; 8 hours per week for 2 years).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for survey data, such as descriptive statistics and analysis of variance will be used to analyze the data. See Part B for detailed information on the design, hypotheses, and analysis plan. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations at trade and academic conferences, publications, articles, and Internet posting.

Table 2. – Project Time Schedule

Task	**Estimated Number of Weeks after OMB Approval**
Pretest completed	8 weeks
Main study data collected	18 weeks
Final methods report completed	24 weeks
Final results report completed	30 weeks
Manuscript submitted for internal review	42 weeks

Manuscript submitted for peer-review journal publication	52 weeks

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.