(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Validated Follow-up Interview of Clinicians on Outpatient Antibiotic Stewardship Interventions—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Code of Federal Regulations under subsections C and D of section 247d–5 authorizes education of medical and health services personnel in antimicrobial resistance and appropriate use of antibiotics and the funding of eligible entities to increase capacity to detect, monitor, and combat antimicrobial resistance. Through the Centers for Disease Control and Prevention's (CDC) SHEPheRD funding mechanism, the University of Utah has been awarded a contract to perform such work as stated above within a research framework in the urgent care setting, with interventions based on the Core Elements of Outpatient Antibiotic Stewardship. Intermountain Healthcare is the subcontractor for this work, and operates the clinics participating in the intervention arm of this research study.

The proposed request for data collection will allow Intermountain Healthcare to explore knowledge, attitudes, and practices among clinicians to identify barriers and facilitators after the implementation of the antibiotic stewardship program in the urgent care setting of participating clinics. CDC requests approval for 207 estimated annualized burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Urgent Care Clinician	Interview Guide	40	1	1
Urgent Care Clinician	Survey	250	1	40/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–14330 Filed 7–2–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3018]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Healthcare Provider Perception of Boxed Warning Information Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by August 5, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comment'' or by using the search function. The title of this information collection is ''Healthcare Provider Perception of Boxed Warning Information Survey.'' 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 Provider Perception of Boxed Warning Information Survey

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 proposed collection of information will investigate healthcare providers' (HCPs') awareness, perceptions, and beliefs about the benefits and risks of an FDA-approved product that carries a boxed warning. The prescribing information for an FDA-approved drug or biologic (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 that medication, described in FDA guidance entitled ''Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biologic Products—Content and Format,'' published in October 2011 (*https://www.fda.gov/media/71866/download*). In certain situations, a drug's prescribing information may include a boxed warning in addition to other sections of the labeling to highlight important safety information about specific serious risks of that drug. Boxed warning information may be included as part of prescribing information at the time of FDA approval. Boxed warning information may also be added or modified to the prescribing information of drugs already on the market on the basis of new safety information.

Boxed warnings are an important and frequently used communication tool. 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 (Ref. 1). However, this review and others have identified several gaps in the existing literature, including the limited number of drugs or drug classes studied (Ref. 2). Further, little research has focused on understanding *how* HCPs receive, process, and use boxed warning information to support their treatment decisions and patient counseling.

To address this research gap, we propose conducting a web-based survey of HCPs. The proposed collection of information will strengthen FDA's understanding of how HCPs may receive, process, and use boxed warning and other safety labeling information. This survey will be conducted as part of a mixed methods research approach 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 prescreening for risk factors or monitoring for adverse events (Ref. 3). 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 indepth individual interviews.

The general research questions in this data collection are as follows:

1. What awareness, knowledge, and beliefs do HCPs have regarding boxed warning information for a prescription drug or class of drugs?

2. When making prescribing decisions, how do HCPs consider boxed warning information about a potential treatment? How does boxed warning information factor into their assessments of a drug's potential benefits and risks to their patients?

3. How do HCPs communicate with their patients about boxed warning information?

4. What factors (e.g., experience treating a condition) are associated with HCPs' awareness, knowledge, and beliefs about boxed warning information?

In order to explore a range of potential perceptions and uses of boxed warning information that may exist under different contexts, this survey research will evaluate two medical product scenarios involving an FDA-approved medication or class of medications that include boxed warning information. The scenarios will include pertinent prescribing information from the FDA-approved labeling for these medications. We plan to conduct one pretest survey with 50 voluntary participants and one main survey with 1,156 voluntary participants. The survey will be conducted online. Survey response is estimated to take no longer than 20 minutes.

Participants in the pretest survey and main survey will be recruited online through a web-based HCP survey research panel. Participants will be HCPs with prescribing authority who prescribe medications to treat one of medical conditions in the medical product scenarios. Participants will include primary care providers (including internal medicine, family medicine, and general medicine, as well as nurse practitioners, and physician assistants) and relevant medical specialists. Participants will be screened for their current amount of time spent in direct patient care, prescribing volume, and experience treating the relevant medical condition. Demographic soft quotas will be used to help ensure that the survey population is generally reflective of the demographic composition of physicians in the United States, according to the American Medical Association.

The pretest and main studies will have the same design and will follow the same procedure. In advance of the pretest survey, we will conduct cognitive testing of the survey questionnaire to refine the survey instruments. The main survey will be refined as necessary following the pretest survey.

In the **Federal Register** of August 8, 2019 (84 FR 38996), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments that were PRA related. 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 1) 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 2) In accordance with the requirements set forth by institutional review boards and OMB, any research must involve voluntary participation of research participants. FDA acknowledges 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 2 overarching comments (3a and 3b below) and 13 additional (3c to 3p) 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 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) FDA agrees 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 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): FDA agrees 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 to 6 to assess the level of experience.

(Response 3c): FDA appreciates 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 to 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 Q4 to 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 the 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 used 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): FDA agrees that there may be a need to differentiate HCPs who initiate vs. those who only prescribe refills for the scenario drug. The 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): FDA agrees 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 to 11 on earlier phase of condition and Q7 to 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 Q12OTH as a separate question. This approach will enable respondents to rank another option.

(Response 3i): FDA agrees 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)'', rather than asking it as a separate question. Should the survey respondent 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): FDA believes 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 for 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): FDA agrees 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 3n): Please provide rationale for the relevance of asking Question 28_H.

(Response 3n): In the questionnaire draft that the commenter reviewed, Q28_H asks respondents to 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, to address this comment, we excluded the question in the revised questionnaire.

(Comment 3o): 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 3o): 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.''). The revised questionnaire, however, excludes the open-ended Q30 in the revised questionnaire, in an effort to streamline the survey and reduce respondent burden.

(Comment 3p): [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 3p): FDA reviewed the survey and added an Unsure/Don't know option where we deemed appropriate: Qs 2, 3, 4, 28, 29. Questions 8 and 25 were removed. 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.

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
Pretest Screener	84	1	84	0.05 (3 minutes)	4
Pretest Informed Consent	50	1	50	0.05 (3 minutes)	2
Pretest Survey Completes	50	1	50	0.28 (17 minutes)	14
Main Survey Screener	1,927	1	1,927	0.05 (3 minutes)	96
Main Survey Informed Consent	1,156	1	1,156	0.05 (3 minutes)	58
Main Survey Completes	1,156	1	1,156	0.28 (17 minutes)	324
Total	4,423				498

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

II. References

The following references are on display with the Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are not available electronically at *https://www.regulations.gov* as these references are copyright protected.

1. Dusetzina, S.B., A.S. Higashi, E.R. Dorsey, 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., S.B. Soumerai, F. Zhang, et al., ''A Critical Review of Methods to Evaluate the Impact of FDA Regulatory Actions.'' *Pharmacoepidemiology Drug and Safety,* 22(9):986–994, 2013.
3. Morgan, M.G., et al., *Risk Communication: A Mental Models Approach.* Cambridge University Press, 2002.

Dated: June 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14377 Filed 7–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2020–N–1228]

Agency Information Collection Activities; Proposed Collection; Comment Request; Study of Multiple Indications in Direct-to-Consumer Television Advertisements

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Study of Multiple Indications in Direct-to-Consumer Television Advertisements.''

DATES: Submit either electronic or written comments on the collection of information by September 4, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 4, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 4, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the