specific process outlined in the draft guidance, but rather addressed support for, or concerns with, the underlying policy of judicious use of medically important antimicrobials in animals, specifically the principle of limiting medically important antimicrobial drugs to uses in animals that include veterinary oversight or consultation. As described in FDA GFI #209, ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'' (77 FR 22328, April 13, 2012), the development of resistance to this important class of drugs, and the resulting loss of their effectiveness as antimicrobial therapies, poses a serious public health threat. Developing strategies to reduce antimicrobial resistance is critically important for protecting both public and animal health. This guidance is an extension of FDA's ongoing efforts to promote the appropriate or judicious use of medically important antimicrobial drugs in animals.

This guidance provides information to sponsors of new animal drug products containing antimicrobials of human medical importance who are interested in changing the approved marketing status of these products from OTC to Rx with specific recommendations on submission of revised labeling. Such changes are consistent with FDA's recommendation that the use of such antimicrobial drugs in animals include veterinary oversight in order to mitigate development of antimicrobial resistance and thereby preserve the effectiveness of these drugs for use as therapies to treat infections in humans and animals. The guidance also identifies timelines for stakeholders wishing to comply voluntarily with this guidance; these timelines remain as outlined in the draft guidance. In the final guidance, editorial changes were made to improve clarity.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommendations for drug sponsors for voluntarily bringing under veterinary oversight all medically important antimicrobial drugs approved for use in animals that continue to be available as OTC products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: June 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12297 Filed 6–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–2079]

Determination of Regulatory Review Period for Purposes of Patent Extension; BRAVECTO; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) published a notice in the **Federal Register** of February 12, 2018. After review of a timely request for reconsideration by the applicant of the determination of the regulatory review period of the animal drug, BRAVECTO, in that notice, FDA has determined that a revision of the **SUPPLEMENTARY INFORMATION** section is warranted. This document presents the revised regulatory review period.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 12, 2018 (83 FR 6033), in FR Doc. 2018–02761, in the first column, the first two paragraphs under the section ''II. Determination of Regulatory Review Period,'' the following correction is made on page 6034:

FDA has determined that the applicable regulatory review period for BRAVECTO is 1,054 days. Of this time, 1,016 days occurred during the testing phase of the regulatory review period, while 38 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) became effective:* June 28, 2011. The applicant claims February 19, 2010, as the date the investigational new animal drug application (INAD) became effective. However, after consideration of additional information presented by the applicant in response to the **Federal Register** notice (83 FR 6033), FDA has determined that the start of the testing phase was June 28, 2011, which was the date the first major health or environmental effects test began.

Dated: June 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12284 Filed 6–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1261]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study of Disclosures to Healthcare Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by July 12, 2021.

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 Comments'' or by using the search function. The title of this information collection is ''Study of Disclosures to Healthcare Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug.'' 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.

Study of Disclosures to Healthcare Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug

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

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

The revised draft guidance entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices'' (2014; Ref. 1),[1] recommends that scientific and medical journal articles that discuss unapproved uses of approved drug products be disseminated with a representative publication that reaches contrary or different conclusions, when such information exists. Similarly, the draft guidance entitled ''Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices'' (2011; Ref. 2) [1] recommends that when conclusions of articles or texts that are disseminated in response to an unsolicited request have been specifically called into question by other articles or texts, a firm should disseminate representative publications that reach contrary or different conclusions regarding the use at issue.

Pharmaceutical firms sometimes choose to disseminate publications to healthcare providers (HCPs) that include data that appear to support an unapproved use of an approved product. At the same time, published data that are not supportive of that unapproved use may also exist. For example, unsupportive published information could describe an increased risk of negative outcomes (*e.g.,* death, relapse) from the unapproved use of the approved product, suggesting that the unapproved use does not have a positive benefit-risk ratio. The purpose of this research is to examine physicians' perceptions and behavioral intentions about an unapproved new use of an approved prescription drug when made aware of other data that are not supportive of the unapproved use. This research will also evaluate the effectiveness of various disclosure approaches for communicating the unsupportive information. We will use the results of this research to better understand: (1) Physicians' perceptions of an unapproved use of a prescription drug; (2) physicians' perceptions about an unapproved use of an approved prescription drug when they are aware of the existence of unsupportive information about it; (3) physicians' perceptions of disclosures referencing the existence of unsupportive information about that particular use; and (4) to examine the utility and effectiveness of various approaches to the communication of this information. In particular, we plan to examine how different approaches to the communication of unsupportive information affect physicians' thoughts and attitudes about the unapproved use. Five approaches will be examined: (1) The provision of the unsupportive data in the form of a representative publication; (2) a disclosure that summarizes, rather than provides, the unsupportive data and includes a citation to the representative publication; (3) a disclosure that does not provide or include a summary of the unsupportive data but does acknowledge that unsupportive data exist and includes a citation to the representative publication; (4) a general disclosure that does not provide or include a summary of the unsupportive data but acknowledges unsupportive data *may* exist, without conceding that such data do exist; or (5) nothing—the absence of any presentation of unsupportive data or any disclosure about such data (control condition). We have four research questions:

RQ1: When considering a presentation of data about an unapproved use of an approved drug product, how does the existence of unsupportive data impact physicians'

[1] When final, this guidance will represent the FDA's current thinking on this topic.

perceptions and intentions with regard to that unapproved use?

RQ2: How does the way in which the existence of unsupportive data is communicated, when the specific data is not presented, impact physicians' perceptions and intentions with regard to an unapproved use of an approved drug product?

RQ3: How are physicians' perceptions of and intentions toward an unapproved use of an approved drug product affected by the disclosure of specific unsupportive data versus disclosure statements about data that is not presented?

RQ4: Do other variables (*e.g.,* demographics) have an impact on these effects? These research questions will be examined in two medical conditions.

We plan to conduct one pretest with 180 voluntary adult participants and one main study with 1,600 voluntary adult participants. Participants in the main study will be 510 oncologists in the oncology medical condition and 1,090 primary care physicians in the insomnia [2] medical condition. All participants will be physicians who engage in patient care at least 50 percent of the time and do not work for a pharmaceutical company, marketing firm, or the Department of Health and Human Services. The gender, race/ethnicity, and ages of the participating physicians will be self-identified by participants. We will aim to include a mix of demographic segments to ensure a diversity of viewpoints and backgrounds. Power analyses were conducted to ensure adequate sample sizes to detect small to medium effects.

The studies will be conducted online. The pretest and main studies will have the same design and will follow the same procedure. The base stimulus in both the pretest and main studies will consist of a sample publication supporting an unapproved use of an approved drug product. Within each medical condition, participants will be randomly assigned to one of five test conditions (see figure 1). Following exposure to the stimuli, they will be asked to complete a questionnaire that assesses comprehension, perceptions, prescribing intentions, and demographics. In the pretest, participants will also answer questions about the study design and questionnaire.

FIGURE 1—STUDY DESIGN

	Accompanied by representative publication with unsupportive data	Accompanied by disclosure with summary of unsupportive data and including a citation for that data	Accompanied by disclosure that unsupportive data exist and including a citation for that data, but without a summary of the unsupportive data	Accompanied by general disclosure that unsupportive data *may* exist and no citation	No disclosure or material about unsupportive data
Medical Condition 1 Medical Condition 2					

In the **Federal Register** of July 6, 2020 (85 FR 40300), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two submissions that were PRA-related. Within these submissions FDA received multiple comments that the Agency has addressed below. For brevity, some public comments are paraphrased and, therefore, may not include the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: HCP = healthcare provider; FDA and ''The Agency'' = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

(Comment 1) One comment asserted that FDA has not made the stimuli available for public comment and requested FDA publish a new 60-day notice after these comments have been addressed to give the public another opportunity to review and comment.

(Response 1) We have provided the purpose of the study, the design, the population of interest, and the questionnaire to individuals upon request. These materials have proven sufficient for public comment and for academic experts to peer review the study successfully. Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise the research.

(Comment 2) One comment suggested that due to the task of reading the ''scientific publication'' stimuli and length of the questionnaire, FDA's estimation of the time it will take to complete the study is too low, and thus the burden of the information collection is inaccurate.

(Response 2) The scientific ''publications'' in this study are each formatted as a one-page brief report. The text is presented in two columns and has the following headings: Introduction, Methods, Results, Discussion, and Limitations. The survey contains primarily closed-ended questions with Likert scales, and there are five open-ended questions. The expected time for the study is based on our prior experience conducting studies using similar protocols. We will also test the time during the pretest to ensure we stay within 20 minutes. If we determine the average time for completing the survey is greater than 20 minutes, we will revise the survey prior to fielding the main study.

(Comment 3) One comment asserts this proposed study overlaps with other OPDP research currently in progress and references several studies.

(Response 3) OPDP may conduct concurrent or overlapping studies on similar topics. While the studies referenced by the comment contribute to the evidence base for prescription drug promotion, prior studies had a different focus than the current study. Prior disclosure studies examined the effectiveness of disclosures in increasing understanding of efficacy claims (''Disclosures in Professional and Consumer Prescription Drug Promotion'') and the role of disclosures in mitigating potentially misleading presentations of preliminary or descriptive data about oncology drugs (''Disclosures of Descriptive

[2] This medical condition was changed from diabetes to insomnia based on cognitive testing.

Presentations in Professional Oncology Prescription Drug Promotion''). The third study mentioned by the comment (''Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces'') investigates how physician perception of professional prescription drug communications is influenced by variations in information context, methodologic rigor of the clinical study, and time pressure.

The current study uses an experimental design to compare various disclosure approaches for communicating unsupportive information about an unapproved new use. The findings of this study will help inform FDA's understanding about when disclosures about unsupportive data might be useful and what types of information should be included.

(Comment 4) One comment expressed concern that the way in which the proposed research is described in the notice suggests that pharmaceutical firms disseminate supportive data but do not adequately disclose unsupportive data and that this ''implied bias'' may taint the collection and interpretation of the data.

(Response 4) The sentences referred to in this comment appear in the **Federal Register** notices for the study to provide background and do not suggest that any firms are not following the recommendations in the two guidance documents referenced in that same background section. Rather, the background outlines the current FDA recommendations around disclosure of unsupportive data with these types of communications and the intent of the study to evaluate alternative approaches to the disclosure of unsupportive data. These background statements are not part of the materials that will be provided to study participants. Rather, study instructions tell participants only that they will be reviewing informational material about a prescription drug. No instructional materials provided to participants mention a pharmaceutical manufacturer. Therefore, we do not believe the collection and interpretation of study findings will be tainted or biased.

(Comment 5) One comment suggested deleting or amending all questions about HCPs' prescribing decisions (Questions 4, 5, 10, 11, 14 to 23) because these decisions are likely to be influenced by many factors and are outside of FDA's jurisdiction. This comment also asserted Question 10 is biased and worded to suggest that pharmaceutical firms disseminate supportive data but do not adequately disclose unsupportive data and suggests deleting or amending the question.

(Response 5) As explained earlier, the Public Health Service Act authorizes FDA to conduct research relating to health information, and the FD&C Act authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act. The purpose of the current experimental study is to examine physicians' perceptions and behavioral intentions about an unapproved new use of an approved prescription drug when made aware of other data that are not supportive of the unapproved use and to evaluate the effectiveness of various disclosure approaches for communicating the unsupportive information. The study is within FDA's authority, and it will help to inform OPDP's work to help ensure that prescription drug information is truthful, balanced, and accurately communicated so that HCPs and consumers can make informed decisions.

Questions 4 and 5 were intended to assess the impact of various disclosure manipulations on hypothetical prescribing decisions. Measuring behavioral intention is a common method of assessing knowledge and attitudes. There is substantial theoretical and empirical support for our approach, and strong behavioral intention has been shown to be predictive across a wide range of behaviors, including prescribing (Refs. 3 to 5). Based on the results of cognitive interviews, we have revised the measurement of behavioral intention to the following: ''If you were considering prescribing [DRUG] to a patient with [DISEASE], how important would the information in the [DISPLAY FILL] be in your decision making?''

Questions 14 to 23 provide important information to address the research questions for this study, including sources of information for studies that do not support an off-label use as well as what aspects of the study would be most important to prescribers.

Questions 10 and 11 are intended to evaluate whether there is enough information for the participants to make a prescribing decision based on the information in the brief study report and disclosure condition, not to assess the adequacy of pharmaceutical firms' disclosure of unsupportive data generally. Pharmaceutical firms are not referenced in any study materials, and these questions do not imply anything about their dissemination activities.

(Comment 6) One comment recommended that the stimuli used to represent publications that reach contrary or different conclusions regarding the unapproved use be held to the same standards as the publication about the unapproved use. The comment suggests that this should include being considered scientifically sound by experts with scientific training and expertise to evaluate the safety or effectiveness of the drug or device.

(Response 6) Both the supportive and unsupportive data provided to study participants either in the form of publications or summary information were reviewed by FDA experts with the requisite scientific training and experience to ensure they are appropriate, realistic, and of similar quality.

(Comment 7) One comment recommended that the disclosure summary include specific information about the study design (*i.e.,* study population and control group, key clinical endpoints (patient outcomes)), statistical significance (*i.e.,* 95 percent confidence interval (CI), hazard ratio (HR) and p value) and other key data needed to determine benefit-risk ratio, and to include the product manufacturer and study sponsor.

(Response 7) The proposed experimental study design includes five conditions to examine disclosure approaches for communicating unsupportive information. One of the five conditions provides study details as recommended by the comment. The other conditions have varying levels of detail about the unsupportive information about the unapproved new use of the prescription drug. There is also a control condition. We have purposely omitted the product manufacturer and study sponsor, as we know from other research this may unduly influence physicians' beliefs about the quality of the study (Ref. 6).

(Comment 8) One comment suggested the disclosure correlate with the unapproved use described in the brief study report.

(Response 8) We agree with this point. The disclosure and unsupportive data provided to participants are relevant to the unapproved use information participants initially review.

(Comment 9) One comment suggested including hyperlinks to a citation for the data and including a representative publication with unsupportive data. This comment also suggested keeping track of how many study participants utilize the hyperlink.

(Response 9) We developed the stimuli for this study using information from multiple scientific publications. Thus, the content does not represent one particular study, and we are unable

to provide hyperlinks. The revised design suggested in the comment may be a good suggestion for future research.

Several comments suggested changes to the proposed questionnaire.

(Comment 10) One comment suggested the instructions and lack of a ''don't know'' response option may lead to forced guessing, which may undermine the utility of the study.

(Response 10) We have deleted Question 10 and revised Question 11 to read, ''What additional information, if any, did you need in order to consider prescribing [DRUG] for [DISEASE]?'' and deleted the instructions to ''give us your best guess on answers you do not know.''

(Comment 11) One comment recommends FDA focus on HCPs' understanding of the data rather than asking about HCPs' preference for receiving information (Q19 and Q20).

(Response 11) In response to the comment, we have removed Questions 19 and 20 from the survey. Question 3 (now Q4) assesses physician understanding of the disclosure.

(Comment 12) One comment suggested deleting or revising Questions 6 and 9 because outside influences could skew the results.

(Response 12) We are examining the impact of the various levels of information disclosure on participants' ratings of how informative they find the information and how likely they would be to search for additional information about the drug. Participants will be randomly assigned to a condition, and any individual differences or potential biases should be spread across experimental conditions. Thus, if we find differences between and among conditions, we can be reasonably certain that the study manipulations caused the differences. In consideration of this comment and feedback from peer reviewers, we have revised Question 6 (now Q7) to read, ''If you were considering prescribing [DRUG] for [DISEASE], how useful would the information [DISPLAY FILL] be?''

(Comment 13) One comment suggested deleting or revising Question 8 because it is unclear what it means for information to be ''credible'' in this context, and assessing credibility is very subjective.

(Response 13) To clarify, this question reads, ''How credible is the information presented [DISPLAY FILL]?'' where [DISPLAY FILL] in Condition 1 is ''on page 2,'' in Conditions 2, 3, and 4 is the text of the disclosure condition to which they have been assigned, and in Condition 5 is ''the material.'' Thus, the information on which participants are being asked to give their opinion is specified. This question has been used in other studies without difficulty. Cognitive testing did not identify any difficulty with respondents' understanding of ''credible'' in this context.

(Comment 14) One comment suggested amending questions that are worded ''contradict or do not support'' because physicians may view a lack of support (inconclusive findings) as different from contradictory findings.

(Response 14) We did not intend for ''do not support'' to mean that the findings are inconclusive, although we acknowledge that it could be interpreted in such a way. Our intention was to refer to any findings that do not support the off-label use, such as findings that the drug is not effective for the off-label use or had increased risks. We explored potential confusion by asking separate questions on the concepts of ''contradict'' and ''inconclusive'' in cognitive testing. Cognitive testing suggested that respondents generally considered ''findings that contradict'' and ''findings that have inconclusive support'' to be very similar concepts. While respondents agreed that the two were technically distinct, they tended to assess the two similarly in this context. To gather additional empirical data, we will retain these as separate items in the pretest.

(Comment 15) One comment suggests many of the questions use unbalanced answer scales and recommends the answer scales should be balanced. For example, it may be difficult for participants to distinguish between ''A little'' and ''Somewhat'' or ''Very'' and ''Extremely.'' Relatedly, the positive and negative options are not necessarily opposites (*e.g.,* ''Agree'' or ''Disagree'') or parallel in intensity (*e.g.,* ''Strongly Agree'' or ''Strongly Disagree'').

(Response 15) We are not using a bipolar scale measuring opposites. Bipolar scales are typically used when there are two opposing possibilities (*e.g.,* ''Strongly Agree'' or ''Strongly Disagree''). We chose a unipolar scale (*e.g.,* ''not at all important'' to ''extremely important'') because the questions are asking about the relative presence or absence of a quality. In the case of usefulness, for instance, it makes more sense for the scale to begin with the absence of usefulness (''not at all useful'') rather than the opposite of usefulness (''extremely useless''). By beginning with ''Not at all,'' the order of the scale balances out the unidimensional nature of the question (Ref. 7). In fact, a key advantage of a unipolar scale is that it does not depend on defining opposites. The scale labels (*i.e.,* ''Not at all,'' ''A little,'' ''Somewhat,'' ''Very,'' and ''Extremely'') have been tested in multiple studies, and evidence shows that participants are able to distinguish between the response options (see, for example, Ref. 8).

(Comment 16) One comment expressed a lack of clarity on how Question 3 could yield interpretable responses and recommended replacing this open-ended question with closed-ended questions.

(Response 16) Open-ended items are often used when the intention is to understand respondents' comprehension (Ref. 9). By asking respondents to rephrase the disclosure in their own words (as if explaining to a colleague), we can assess whether respondents understand the disclosure language as intended (Ref. 10). The responses to open-ended items are qualitative data and will be analyzed to assess what respondents feel to be key information (information included in their summary), what they feel is extraneous information (information *not* included in their summary), and any information that is confusing or unclear (information summarized incorrectly in the summary).

(Comment 17) One comment suggested adding the following questions to the questionnaire:

1. How often do you research and study off-label uses of approved drugs in a given week? With possible answer choices being ''never, rarely, occasionally, frequently.''

2. How often are drug products used off-label in your practice? With possible answer choices being ''never, rarely, occasionally, frequently.''

3. Would you prescribe this drug for (unapproved use of an approved drug product)? With possible answer choices being: ''yes, no, need more information.''

(Response 17) For the first suggested question, we currently assess frequency of prescribing a drug off label (Q14) and the sources used to learn about off-label uses (old Q15 and old Q16, now Q17, Q18, and Q19). We think this combination of questions adequately covers the concept of how often participants prescribe and look for information about off-label uses. Regarding the response choices, the timeframe of a week is very narrow, and would be difficult to answer for those who prescribe off-label infrequently (*e.g.,* a few times a year). In response to the comment and external peer review comment, we have revised response options for Q14 to be more specific (*once a week or more often, several times each month, several times each*

year, less than once a year, have never prescribed a drug for an off-label use).

For the second suggestion, we agree that the frequency of prescribing within the practice would be useful to capture and have added a question to measure this. No difficulties were identified with this question during cognitive testing.

For the third suggestion, we agree that this would be a useful measure. In response to this comment and peer review, we have revised the questionnaire to ask about prescribing likelihood for the specific off-label use.

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	290	1	290	0.08 (5 minutes)	23
Pretest completes	180	1	180	0.33 (20 minutes)	59
Main study screener	2,526	1	2,526	0.08 (5 minutes)	202
Main study completes, Medical Condition 1	510	1	510	0.33 (20 minutes)	168
Main study completes, Medical Condition 2	1,090	1	1,090	0.33 (20 minutes)	360
Total	1,600				812

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

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices—Revised Draft Guidance,'' 2014. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf.*

*2. ''Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices Draft Guidance,'' 2011. *https://www.fda.gov/media/82660/download.*

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Dated: June 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12265 Filed 6–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0371]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 the proposed study entitled ''Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug websites.''

DATES: Submit either electronic or written comments on the collection of information by August 10, 2021.

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 August 10, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 10, 2021. Comments received by mail/hand delivery/courier (for written/paper