CDER or CBER by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify any new standards and version updates, when the support begins or ends, and when the requirement begins or ends, that will be added to the Catalog. Support for version 1.7 of the CDISC SDTM IG 3.3 and version 2.1 of the Define-XML will begin on March 15, 2021, and the date that the requirement begins will be on March 15, 2022, for NDAs, ANDAs, and certain BLAs. For noncommercial INDs, the date that requirement begins will be March 15, 2023. Support and requirement ended for version 1.3 of the CDISC SDTM IG 3.1.3 will end on March 15, 2021.

Dated: June 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14512 Filed 7–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1307]

Agency Information Collection Activities; Proposed Collection; Comment Request; Examination of Secondary Claim Disclosures and Biosimilar Disclosures in Prescription Drug Promotional Materials

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 research entitled, ''Examination of Secondary Claim Disclosures and Biosimilar Disclosures in Prescription Drug Promotional Materials.''

DATES: Submit either electronic or written comments on the collection of information by September 8, 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 8, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 8, 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 manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1307 for ''Examination of Secondary Claim Disclosures and Biosimilar Disclosures in Prescription Drug Promotional Materials.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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.*

For copies of the questionnaire contact: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined

in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Examination of Secondary Claim Disclosures and Biosimilar Disclosures in Prescription Drug Promotional Materials

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 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) mission is to protect the public health by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated, so that patients and health care providers can make informed decisions about treatment options. 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, including content and format, 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 (DTC) advertisements conducted in 1999.

The purpose of this research is to build on prior FDA research on the topic of disclosures by examining the impact of disclosures of two different types of information, detailed later in this notice. The literature on disclosures suggests their effectiveness is subject to format, design, and audience factors, among other things (Ref. 1). For example, research on consumer attitudes have found some people believe that FDA evaluates certain dietary supplement claims despite the presence and consumer awareness of language required by the Dietary Supplement Health and Education Act, which clearly states that FDA has not evaluated those claims (Refs. 2 and 3). In the context of prescription drug promotion, there is initial evidence that—when noticed—disclosures may effectively convey important information (Refs. 4 to 6); however, what role disclosures may play in educating or correcting misunderstanding warrants further investigation.

In the new study proposed here, the first type of disclosed information we will examine is clinical benefit information based on a secondary endpoint reported in a product's approved labeling (a secondary claim). In some cases, truthful and non-misleading presentations about secondary endpoints in well-designed clinical studies can provide reliable information about treatment effects that may be distinct from the treatment effects described in the product's indication statement. For example, a product may be indicated to treat a specific type of cancer based on a primary endpoint of survival. However, a secondary endpoint in the study of that product may provide data about an additional distinct benefit, such as functional status.

Phase 1 of the proposed research will examine the impact of adding a disclosure about a secondary claim in DTC and healthcare professional (HCP)-directed promotion in the context of a prescription drug website. We will also examine the effect of the presence of a comparative claim about the secondary claim. Our proposed main outcome measures are perceptions of and attitudes toward the product, the secondary claim, and the disclosure. The pretest and main studies for Phase 1 will have the same design, will be conducted online, and will follow the same procedure. We will examine four levels of secondary claim disclosure to explore the effects of disclosing that the secondary benefit is not one of the indicated uses of the product (*e.g.,* not a treatment for [the secondary benefit claim], quantitative information about claim, not a treatment for [claim] and quantitative information about claim, or no disclosure), and two levels (presence or absence) of a comparative element regarding the secondary claim, for a total of eight experimental conditions (see table 1). Participants will be randomly assigned to one of these conditions; they will view one version of a website. This 4×2 design will be replicated across two target populations (HCPs and consumers).

TABLE 1—PHASE 1 STUDY DESIGN

Phase 1: Secondary claim disclosure by comparative secondary claim in online prescription drug websites				
Comparative secondary claim	Secondary claim disclosure			
	"Drug X is not a treatment for [claim]"	"In a clinical trial, participants [quantitative information] on Drug X"	"Drug X is not a treatment for [claim]" AND "In a clinical trial, participants [quantitative information] on Drug X."	None (no secondary claim)
HCPs:				
Present: Compared to [xx] on Drug Y.				
Absent.				
Consumers:				
Present: Compared to [xx] on Drug Y.				
Absent.				

The second, independent phase of the proposed research will examine disclosures about a biosimilar product. In both consumer and HCP audiences, we will assess the impact of a disclosure designating the product as a biosimilar as well as varying basic factual statements about biosimilars. Phase 2 will examine the impact of: (1) Adding a disclosure designating the product as a biosimilar; (2) adding general informational statements about biosimilars; and (3) naming a reference product. This approach allows us to examine the effect of disclosing biosimilar status, examines the additive effect of including one, two, or three additional basic statements of information about biosimilars, and measures the effect of naming the reference product. Our proposed main outcome measures are perceptions of and attitudes toward the biosimilar product and the disclosure.

We propose to examine seven different disclosure conditions plus a control with no disclosure for a total of eight test conditions. As a baseline, each of the seven disclosure conditions will include a statement that the drug is a biosimilar. Six of the seven disclosure conditions will include this baseline statement and will vary the amount of additional basic factual information about biosimilar products in the following way: (1) Two of the six conditions have the baseline + statement A; (2) two of the six conditions have the baseline + statement A + statement B; and (3) two of the six conditions have the baseline + statement A + statement B + statement C. Moreover, three of the six disclosure conditions will name the specific reference product while the other three will refer to a reference product generally (for example, ''This biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product''). The wording of the disclosure will be tailored to the audience; for example, the disclosures for the consumer audience will avoid technical terms. A control condition will also be included in which no biosimilar statement or additional information disclosure is presented.

The pretest and main studies for Phase 2 will have the same design, will be conducted online, and will follow the same procedure. Both phases will be conducted concurrently. Sample sizes were determined on the basis of power analysis that will allow us to detect medium effect sizes.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Phase 1 Pretest screener (HCPs)	432	1	432	.08 (5 minutes)	35
Phase 1 Pretest screener (consumers)	432	1	432	.08 (5 minutes)	35
Phase 1 Pretest completes (HCPs)	238	1	238	.33 (20 minutes)	79
Phase 1 Pretest completes (consumers)	238	1	238	.33 (20 minutes)	79
Phase 2 Pretest screener (HCPs)	112	1	112	.08 (5 minutes)	9
Phase 2 Pretest screener (consumers)	112	1	112	.08 (5 minutes)	9
Phase 2 Pretest completes (HCPs)	62	1	62	.33 (20 minutes)	21
Phase 2 Pretest completes (consumers)	62	1	62	.33 (20 minutes)	21
Phase 1 screener (HCPs)	720	1	720	.08 (5 minutes)	58
Phase 1 screener (consumers)	720	1	720	.08 (5 minutes)	58
Phase 1 completes (HCPs)	396	1	396	.33 (20 minutes)	131
Phase 1 completes (consumers)	396	1	396	.33 (20 minutes)	131
Phase 2 screener (HCPs)	1,040	1	1,040	.08 (5 minutes)	83
Phase 2 screener (consumers)	1,040	1	1,040	.08 (5 minutes)	83
Phase 2 completes (HCPs)	572	1	572	.33 (20 minutes)	189
Phase 2 completes (consumers)	572	1	572	.33 (20 minutes)	189
Total	7,144		7,144		1,210

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

References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. 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. Andrews, J.C. (2011). ''Warnings and Disclosures.'' In *Communicating Risks and Benefits: An Evidence-Based User's Guide.* Fischhoff, B., N.T. Brewer, and J.S. Downs, (Eds). FDA: Silver Spring, MD, pp. 149–161.
2. Russo France, K. and P. Fitzgerald Bone (2005). ''Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels.'' *Journal of Consumer Affairs,* 39(1), 27–51.
3. Mason, M.J. and D.L. Scammon (2011). ''Unintended Consequences of Health Supplement Information Regulations: The Importance of Recognizing Consumer Motivations.'' *Journal of Consumer Affairs,* 45(2), 201–223.
4. Betts, K.R., K.J. Aikin, V. Boudewyns, M. Johnson, et al. (2017). ''Physician Response to Contextualized Price-Comparison Claims in Prescription Drug Advertising.'' *Journal of Communication in Healthcare,* 10(3), 195–204.
5. Betts, K.R., V. Boudewyns, K.J. Aikin, C. Squire, et al. (2018). ''Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements.'' *Research in Social and Administrative Pharmacy,* 14(10), 951–963.
6. Sullivan, H.W., A.C. O'Donoghue, K.T. David, and N.J. Patel (2018). ''Disclosing Accelerated Approval on Direct-To-Consumer Prescription Drug websites.'' *Pharmacoepidemiology and Drug Safety,* 27(11), 1277–1280.

Dated: June 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14514 Filed 7–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1538]

Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next PDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by August 17, 2020. Stakeholder meetings will be held monthly. It is anticipated that they will commence in September 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to *PDUFAReauthorization@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of PDUFA. PDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of human drugs. The authorization for the current program (PDUFA VI) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process.

Section 736B(f)(1) of the FD&C Act (21 U.S.C. 379h–2(f)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next PDUFA program. FDA will initiate the reauthorization process by holding a public meeting on July 23, 2020, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in September 2020.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, healthcare professional associations, as well as scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on PDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all stakeholder consultation discussions while FDA