were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN, BY ANTICIPATED DATA COLLECTION METHODS

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interview Screening.	4,800	1	4,800	0.08 (5 minutes)	384
Individual In-Depth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening.	10,800	1	10,800	0.08 (5 minutes)	864
Focus Group/Small Group Discussion.	3,600	1	3,600	1.5	5,400
Observation Screening	720	1	720	0.08 (5 minutes)	58
Observations	144	1	144	2	288
Total	20,464				7,394

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

The total estimated annual burden is 7,394 hours and 20,464 responses. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new collection will vary, depending on the nature of the compliance efforts and the target audience.

The estimated burden hours for focus groups for this collection of information have been increased from the burden published in the **Federal Register** on February 10, 2020, to the burden published in this **Federal Register** notice. The adjustment in burden hours reflects the increased need for this type of data collection across the above-mentioned topic areas.

Dated: June 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14365 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–1261]

Agency Information Collection Activities; Proposed Collection; Comment Request; Study of Disclosures to Health Care 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 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 research entitled ''Study of Disclosures to Health Care Providers Regarding Data that Do Not Support Unapproved Use of an Approved Prescription Drug.''

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 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–1261 for ''Study of Disclosures to Health Care Providers Regarding Data that Do Not Support Unapproved Use of an Approved Prescription Drug.'' 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.

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

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.

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),[1] recommends that information such as reprints, clinical practice guidelines, and textbooks that discuss unapproved uses of approved drug products be disseminated with a representative publication that reaches contrary or different conclusions, when

[1] ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices; Revised Draft Guidance'' (2014). Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/distributing-scientific-and-medical-publications-unapproved-new-uses-recommended-practices-revised.*When final, this guidance will represent FDA's current thinking on this topic.

such information exists. Similarly, the draft guidance entitled ''Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices'' (2011) [2] 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 health care professionals (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 HCPs' 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) HCPs' perceptions of an unapproved use of a prescription drug; (2) HCPs' perceptions about an unapproved use of an approved prescription drug when they are aware of the existence of unsupportive information about it; (3) HCPs' perceptions of disclosures referencing the existence of unsupportive information about that particular use; and (4) 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 physician's 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 summarizing the unsupportive data and including a citation to the representative publication; (3) a disclosure that does not 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 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 HCP perceptions and intentions with regard to that unapproved use?

RQ2: Without presenting the specific unsupportive data, how does the way in which the existence of unsupportive data is communicated impact HCPs' perceptions and intentions with regard to an unapproved use of an approved drug product?

RQ3: How are HCP perceptions of and intentions towards an unapproved use of an approved drug product affected by the disclosure of specific unsupportive data versus disclosure statements about this data that do not include the data itself?

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 diabetes 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 HCPs 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.

[1] ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices; Revised Draft Guidance'' (2014). Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/distributing-scientific-and-medical-publications-unapproved-new-uses-recommended-practices-revised.*When final, this guidance will represent FDA's current thinking on this topic.

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					

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.

Dated: June 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14372 Filed 7–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Practitioner Data Bank Continues Temporary Waiver of User Fees for Eligible Entities

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to its authority under Federal regulations for the National Practitioner Data Bank (NPDB), HRSA's Division of Practitioner Data Bank announces a continuation of its temporary waiver of user fees for NPDB queries from March 1, 2020, through September 30, 2020, to support our eligible entities in making credentialing, hiring, privileging, and licensing decisions in combatting the COVID–19 pandemic. The waiver includes all one-time queries and continuous queries during the waiver time period. Fees for self-queries will not be waived. The NPDB is a confidential information clearinghouse created by Congress and is intended to facilitate a comprehensive review of the professional credentials of health care practitioners, entities, providers, and suppliers. In response to President Trump's declaration of a national emergency and associated emergency declarations by all states, the Federal Government, state governments, and many health care entities have taken unprecedented steps regarding licensure portability and the deployment of health workforce resources, including the expansion of telemedicine and granting of disaster privileges. HRSA's NPDB is in a unique position to temporarily waive fees, granting NPDB access to the nation's hospitals, health centers, health plans, state licensing boards, Federal agencies, and other eligible health care entities in support of their efforts to mobilize and appropriately deploy health workforce professionals.

DATES: The NPDB waiver announcement published on April 17, 2020 (85 FR 21447), was effective retroactively from March 1, 2020, through May 31, 2020. This update continues the waiver through September 30, 2020.

FOR FURTHER INFORMATION CONTACT: David Loewenstein, Director, Division of Practitioner Data Bank, Bureau of Health Workforce, HRSA, (301) 443–2300, *NPDBPolicy@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The NPDB will waive fees retroactively from March 1, 2020, through September 30, 2020, for eligible entity queries (one-time query and continuous query). The NPDB will not refund the cost of queries performed prior to the announcement of the waiver, but will issue query credits to reimburse entities for one-time and continuous queries performed and paid for during the waiver period. Regulations regarding the NPDB are codified at 45 CFR part 60.

Thomas J. Engels,

Administrator.

[FR Doc. 2020–14291 Filed 7–2–20; 8:45 am]

BILLING CODE 4165–15–P