requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information under 21 CFR part 312 (Investigational New Drug Application) have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: August 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16994 Filed 8–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3018]

Agency Information Collection Activities; Proposed Collection; 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 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 Healthcare Provider Perception of Boxed Warning Information Survey.

DATES: Submit either electronic or written comments on the collection of information by October 7, 2019.

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 October 7, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2019. 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–2019–N–3018 for ''Healthcare Provider Perception of Boxed Warning Information Survey.'' 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.gpo.gov/fdsys/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.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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.

Healthcare Provider Perception of Boxed Warning Information Survey

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 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 under 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 25 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.

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	42	1	42	0.05 (3 minutes)	2
Pretest Informed Consent	25	1	25	0.05 (3 minutes)	1
Pretest Survey Completes	25	1	25	0.28 (17 minutes)	7
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			4,331		488

[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; they are not available electronically at *https://www.regulations.gov* as these references are copyright protected. 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. Dusetzina, S.B., et al., ''Impact of FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review.'' *Medical Care,* 50(6):466–478, 2012.
2. Briesacher, B.A., et al., ''A Critical Review of Methods to Evaluate the Impact of FDA Regulatory Actions.'' *Pharmacoepidemiology Drug and Safety.* 22(9):986–994, 2013.
3. Morgan, M.G. et al., *Risk Communication: A Mental Models Approach.* Cambridge University Press, 2002.

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16935 Filed 8–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Scholarships for Disadvantaged Students Program OMB No. 0915–0149—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 7, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Scholarships for Disadvantaged Students Program

OMB No. 0915–0149—Revision

Abstract: HRSA seeks to update the Scholarships for Disadvantaged Students (SDS) program-specific form to collect 3 years of student data instead of 1 year of student data from SDS program applicants. This will assist the agency in making funding decisions for SDS program awards. The form will reflect programmatic changes to the SDS program, made after consideration of the comments received in response to the request for public comment, published at 84 FR 23571, which will be finalized in the forthcoming SDS Policy Change **Federal Register** Notice.

Need and Proposed Use of the Information: The purpose of the SDS Program is to make grant awards to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions programs. To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the Public Health Service (PHS) Act). To meet this requirement, a school must show that at least 20 percent of the school's full-time enrolled students and graduates are from a disadvantaged background. HRSA previously required schools to demonstrate this percentage by submitting 1 year of data; a school must now provide this data for the most recent 3-year period. The proposed revisions to the SDS program-specific form will require applicants to provide the percentage of full-time enrolled students and graduates from a disadvantaged background over a 3-year period, consistent with this policy change.

An additional change to the SDS program is that a 3-year average, instead of a 1-year average, will be used to calculate priority points, which are provided to eligible schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act). The proposed revisions to the SDS program-specific form will require applicants to