collection workgroup composed of State AT program staff that met with ACL on several occasions to suggest revisions to the current instrument. The workgroup identified minor changes in several sections of the instrument, including the reporting of state-level and state leadership activities. For example, AT Device Reassignment and Open-Ended Loan have been combined into a single line in ''A. Recipient Table.'' This update aligns the AT APR with the State Plan for AT structure and will streamline data reporting by grantees. A separate module has been created for all the General Information for State AT programs that is consistent between the AT APR and the State Plan for AT. Data will be entered once and from that point forward only updates will be needed, which will streamline the data entry process for grantees. The Public Awareness table with numeric data has been replaced with two narrative text boxes. Numeric data reported in this section has been historically estimated with little consistency in how data is reported between grantees. With a shift to more electronic information sharing, quantified public awareness data is difficult to report for all grantees and aggregate data is not useful. This change will allow for qualitative data that is more helpful in understanding the activities conducted. The workgroup solicited feedback from all of the grantees through face-to-face meetings and webinar presentations. The number of hours is multiplied by 56 AT State Grants programs, resulting in a total estimated hour burden of 22,624 hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Grants for AT Annual Progress Report (AT APR)	56	1	80.0	4,480
Performance Measure Surveys	56	1	54.0	3,024
Customer Satisfaction Surveys	56	1	54.0	3,024
Data Entry for the Instruments	56	1	208.0	11,648
Record Keeping Burden	56	1	8.0	448
Total	56	1	404.0	22,624

Estimated Total Annual Burden Hours: 22,624.

Dated: September 27, 2017.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2017–21259 Filed 10–3–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5624]

Agency Information Collection Activities; Proposed Collection; Comment Request; Content and Format of Labeling for Human Prescription Drugs and Biological Products; Requirements for Pregnancy and Lactation Labeling

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the content and format requirements for pregnancy and lactation labeling for human prescription drugs and biological products.

DATES: Submit either electronic or written comments on the collection of information by December 4, 2017.

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 December 4, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 4, 2017. 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–2017–N–5624 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Content and Format of Labeling for Human Prescription Drugs and Biological Products; Requirements for Pregnancy and Lactation Labeling.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 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, including each proposed extension of an existing 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.

Content and Format of Labeling for Human Prescription Drugs and Biological Products; Requirements for Pregnancy and Lactation Labeling

OMB Control Number 0910–0624—Extension

This information collection supports Agency regulations regarding the content and format requirements for pregnancy and lactation labeling. In the **Federal Register** of December 4, 2014 (79 FR 72064), FDA published a final rule entitled ''Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling.'' The final rule amended FDA regulations concerning the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section of the labeling for human prescription drugs. The regulations now require, among other things, a summary of the risks of using a drug during pregnancy and lactation and a discussion of the data supporting that summary. The labeling must also include relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. The final rule eliminated the pregnancy categories A, B, C, D, and X. In addition, FDA eliminated the ''Labor and delivery'' subsection because the ''Pregnancy'' subsection includes information on labor and delivery. The final rule also required that labeling include relevant information about pregnancy testing, contraception, and infertility for health care providers prescribing for females and males of reproductive potential. In addition, the final rule provided for a 10-year implementation schedule for compliance with the relevant regulations. As the implementation schedule is realized, FDA plans to discontinue this separate information collection and incorporate the provisions into existing collections, as appropriate.

The content and format requirements apply to:

• Applications submitted on or after June 30, 2015 (§§ 314.50 (21 CFR 314.50), 314.70(b), 601.2 (21 CFR 601.2), and 601.12(f)(1));

• amendments to applications pending on June 30, 2015 (§§ 314.60 (21 CFR 314.60), 601.2, and 601.12(f)(1));

• supplements to applications approved from June 30, 2001 to June 30, 2015 (§§ 314.70(b) and 601.12(f)(1)); and

• annual reports for applications approved before June 30, 2001, that contain a pregnancy category, to report removal of the pregnancy category letter in their labeling (§§ 314.70(d) and 601.12(f)(3)).

Under 21 CFR 201.57(c)(9)(i) and (ii)), holders of approved applications must provide new labeling content in a new format—that is, to rewrite the pregnancy and lactation portions of each drug's labeling. Section 201.57(c)(9)(iii) requires that labeling must include the new subsection 8.3, ''Females and males of reproductive potential.'' Application holders are required to submit prior approval supplements to their approved applications before distribution of the new labeling, as required in § 314.70(b) (21 CFR 314.70(b)) or § 601.12(f)(1) (21 CFR 601.12(f)(1)).

Under 21 CFR 201.80(f)(6)(i), holders of approved applications are required to remove the pregnancy category designation (*e.g.,* ''Pregnancy Category C'') from the ''Pregnancy'' subsection of the ''Precautions'' section of the labeling. These application holders must report the labeling change in their annual reports, as required in § 314.70(d) or § 601.12(f)(3).

As indicated in Tables 1 and 2 of this document, we estimate that the burden associated with the information collection to be 1,598,000 hours.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supplements to applications approved 6/30/01 to 6/30/15 (§§ 314.70(b), 601.12(f)(1)).	390	26	10,140 (Submitted 3rd, 4th, and 5th years after 6/30/15).	120	1,216,800
Annual report submission of revised labeling for applications that contain a pregnancy category, approved before 6/30/01 (§§ 314.70(d), 601.12(f)(3)).	320	~17	5,500 (Submitted 3rd year after 6/30/15).	40	220,000
Total	.....	.....	.....	.....	1,436,800

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
New Drug Applications (NDAs)/Abbreviated New Drug Applications (ANDAs)/Biologics License Applications (BLAs)/efficacy supplements submitted on or after 6/30/15, including amendments to applications pending as of 6/30/15 (§§ 314.50) 314.60, 314.70(b), 601.2, 601.12(f)(1)).	390	~10	4,000 (Submitted during 10-year period after 6/30/15).	40	160,000

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

FDA estimates that approximately 4,000 applications containing the subject labeling will be submitted by approximately 390 applicants and repackagers and relabelers to FDA over the 10-year period beginning June 30, 2015. This figure (4,000 applications) includes labeling for approximately 800 applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 505(b)) or section 351 of the Public Health Service Act (42 U.S.C. 262), 1,200 applications submitted under section 505(j) of the FD&C Act, and 2,000 revised drug product labeling from repackagers and relabelers for approximately 2,000 applications. This estimate also includes labeling amendments submitted to FDA for applications pending as of the effective date of the final rule. FDA estimates that it will take applicants approximately 40 hours to prepare and submit the subject labeling. This estimate applies only to the requirements of the final rule and does not indicate the total hours required to prepare and submit complete labeling for these applications. The information collection burden to prepare and submit labeling in accordance with §§ 201.56 (21 CFR 201.56), 201.57, and 201.80 is approved by OMB under control numbers 0910–0572 and 0910–0001.

In addition, during the 3rd, 4th, and 5th years after the effective date of the final rule, the Agency estimates that it will receive approximately 10,150 supplements to applications that were either approved from June 30, 2001, to the effective date or were pending as of the effective date. This estimate includes supplements for approximately 1,080 NDAs, BLAs, and efficacy supplements; 1,320 ANDA supplements; and 7,750 drug product labeling supplements from repackagers and relabelers. FDA estimates that approximately 390 application holders, repackagers, and relabelers will submit these supplements, and that it will take approximately 120 hours to prepare and submit each supplement.

FDA also estimates that application holders will submit approximately 5,500 annual reports to FDA during the third year after the effective date for applications that contain a pregnancy category, approved before June 30, 2001. This estimate includes approximately 1,340 NDAs and BLAs, and approximately 4,160 ANDAs containing labeling changes as a result of the final rule. FDA estimates that approximately 320 application holders will submit these annual reports, and that it will take approximately 40 hours for each submission.

Dated: September 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21292 Filed 10–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Patient Engagement Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; amendment.

SUMMARY: The Food and Drug Administration (FDA) is announcing amendments to the notice of meeting of the Patient Engagement Advisory Committee. This meeting was announced in the **Federal Register** of July 26, 2017. The amendments are being made to reflect time changes in the **DATES** and *Procedure* sections and to add *Webcast Information* to the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug