(4) *Youth discussions topic guide:* We will hold discussions with youth from target populations about their perceptions of PREP-related programming.

Respondents: Grantees and their independent evaluators; and youth from target populations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent (annually)	Average burden hours per response	Annual burden hours
(1) Abstract template	29	29	1	3	87
(2) CONSORT diagram template	29	29	2	1	58
(3) Baseline equivalence template	16	16	2	2	64
(4) Youth discussions topic guide	64	21	*1	1.5	32

*Total.

Estimated Total Annual Burden Hours: 241.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–16671 Filed 8–7–17; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0349]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-Market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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.

DATES: Fax written comments on the collection of information by September 7, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0771. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-Market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report); OMB Control Number 0910–0771—Extension

The International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use issued, on November 15, 2012, the ICH harmonized tripartite guideline entitled ''Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)'' (the PBRER guideline) (available at *https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html*). The PBRER guideline is intended to promote a consistent approach to periodic post-marketing safety reporting among the ICH regions, to enhance efficiency and reduce burden by reducing the number of reports generated for submission to the regulatory authorities. The PBRER is intended to provide a common standard for periodic reporting on approved drugs or biologics among the ICH regions.

FDA currently has OMB approval for the required submission of periodic adverse drug experience reports (PADER) for drugs subject to a new drug application (NDA) or an abbreviated new drug application (ANDA) (§ 314.80(c)(2) (21 CFR 314.80(c)(2)) (OMB control number 0910–0230), and for the required submission of periodic adverse experience reports (PAER) for drugs subject to a biologics license application (BLA) (§ 600.80(c)(2) (21 CFR 600.80(c)(2)) (OMB control number 0910–0308).

There is considerable overlap in the information required under §§ 314.80(c)(2) and 600.80(c)(2) and the information requested in a periodic safety report using the ICH E2C(R2) PBRER format. Applicants subject to periodic safety reporting requirements under FDA regulations could choose to continue to submit the reports as specified in those regulations, and would be permitted to submit reports in the PBRER format and submit reports as specified in FDA regulations with an approved waiver. Companies who submit periodic reports on the same drug to multiple regulators, including not only the United States, but, also the European Union, Japan, and regulators in other countries who have elected to adopt the ICH standards, may find it in their interest to prepare a single PBRER, rather than preparing multiple types of reports for multiple regulators. As a result, FDA, in the **Federal Register** of November 29, 2016 (81 FR 85976), announced the availability of the guidance for industry entitled ''Providing Post-marketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)'' to indicate its willingness to accept post-market periodic safety reports using the ICH PBRER format in lieu of the specific reports described in FDA regulations.

Because FDA regulations in §§ 314.80(c)(2) and 600.80(c)(2) include specific requirements for periodic safety reports, in order for an applicant to submit an alternative report, such as the PBRER, for a given product, FDA must grant a waiver. Existing regulations permit applicants to request waivers of any post-marketing safety reporting requirement, and the information collections associated with such waiver requests generally are approved under existing control numbers. (See § 314.90(a), waivers for drugs subject to NDAs and ANDAs, approved under OMB control number 0910–0001, and § 600.90(a), waivers for products subject to BLAs, approved under OMB control number 0910–0308.) The November 29, 2016, guidance both explains conditions under which applicants that have previously received waivers to submit reporting information in the format of the previous ICH guidance would be permitted to apply those existing waivers to the submission of PBRERs, and also advises how applicants that have not previously obtained a waiver may submit waiver requests to submit the PBRER.

There are information collections proposed in the November 29, 2016, guidance that are related to waivers specifically to enable the submission of PBRERs, and these information collections are not already addressed under the approved control numbers covering waiver submissions and periodic safety reports generally. FDA has previously granted waiver requests, submitted under §§ 314.90(a) and 600.90(a), that allow applicants to prepare and submit reports using the periodic safety update report (PSUR) format described in FDA's 1996 and 2004 ICH E2C guidance. In accordance with the recommendations of the November 29, 2016, guidance, if an applicant already has a PSUR waiver in place for a given approved application, FDA will consider the existing PSUR waiver to allow the applicant to submit a PBRER instead of a PSUR because the PBRER replaces the PSUR for post-marketing periodic safety reporting for that application. The applicant would not need to submit a new waiver request unless the applicant wishes to change the frequency of reporting. FDA will consider requests to be waived of the quarterly reporting requirement but will not waive applicants of the annual reporting requirement.

If an applicant submits a PBRER in place of the PSUR and uses a different data lock point, the applicant should submit overlapping reports or submit a one-time PADER/PAER in order to cover the gap in reporting intervals. The applicant should submit notification to the application(s), indicating the change in data lock point and should include a description of the measures taken to ensure that there are no resulting gaps in reporting.

If an applicant submits a PBRER in place of the PSUR and uses a different reporting frequency for the PBRER than was used for the PSUR, the continued validity of the waiver will be conditioned on the submission of a PADER/PAER as needed to fulfill the reporting frequency requirement under FDA regulations. The applicant should submit a notification to the application(s), describing this change and the measures taken to ensure that the periodicity requirements are being met.

FDA expects approximately 187 waiver requests and notifications to include the additional information described previously in this document for using a different data lock point and/or for using a different reporting frequency when submitting a PBRER. FDA expects approximately 55 applicants to make these submissions, and we estimate that the time for submitting the additional information described previously would be on average approximately 1 hour for each waiver request or notification.

If an applicant does not have a PSUR waiver in place for an approved application, the applicant may submit a waiver request under § 314.90(a) or § 600.90(a) to submit a PBRER instead of the PADER/PAER. The applicant should submit a request to FDA for each approved application for which a waiver is requested, and a single waiver request letter can include multiple applications. Waiver requests should be submitted to each of the application(s) in the request, and may be submitted electronically or by paper as described in the November 29, 2016, guidance. Each PBRER waiver request should include the following information:

- The product name(s) and application number(s);
- a brief description of the justification for the request;
- the U.S. approval date for the product(s) and current reporting interval used;
- the reporting interval of the last PADER/PAER submitted for the product(s); and
- the data lock point that will be used for each PBRER. If a data lock point other than one aligned to the U.S. approval date is proposed, the applicant should describe how he/she will ensure that there are no gaps in reporting intervals (*e.g.,* by submitting overlapping reports; submitting a one-time PADER/PAER to cover the gap period; or, if the gap is less than 2 months, extending the reporting interval of the final PADER/PAER to close the gap).
- The frequency for submitting the PBRER, as described in section IV.C of the April 8, 2013, draft guidance.
- The email address and telephone number for the individual who can provide additional information regarding the waiver request.

As explained earlier, existing regulations at § 314.90(a) or 600.90(a) permit applicants to request waivers of any post-marketing safety reporting requirement, and the information collections associated with such waiver requests generally are approved under OMB control numbers 0910–0001 and 0910–0308. FDA believes that the information submitted under numbers 1–4 and number 7 in the list in the previous paragraph is information that is typical of any waiver request regarding post-marketing safety reporting and is accounted for in the existing approved collections of information for waiver requests and reports. Concerning numbers 5 and 6, FDA expects approximately 67 waiver requests to include the additional information for using a different data lock point and/or for using a different

reporting frequency when submitting a PBRER. FDA expects approximately 29 applicants to make these submissions, and we estimate that the time for submitting the additional information described in the previous paragraph would be on average approximately 2 hours for each waiver request.

In the **Federal Register** of May 23, 2017 (82 FR 23578), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

We therefore estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Additional information and/or notifications for using a different data lock point and/or a different reporting frequency	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Applicants that have a PSUR waiver for an approved application	55	3.4	187	1	187
Applicants that do not have a PSUR waiver for an approved application	29	2.3	67	2	134
Total					321

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

Dated: August 2, 2017.

Anna K. Abram,

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

[FR Doc. 2017–16647 Filed 8–7–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1848]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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: Fax written comments on the collection of information by September 7, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0599. 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, 10A63, 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.

Cosmetic Labeling Regulations—21 CFR Part 701

OMB Control Number 0910–0599—Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

FDA's cosmetic labeling regulations are published in part 701 (21 CFR part 701). Four of the cosmetic labeling regulations have information collection provisions. Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product.

In the **Federal Register** of May 23, 2017 (82 FR 23576), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received which described ingredients used in the creation of cosmetics but was not PRA-related and will not be addressed here.

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

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

21 CFR section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
701.3—Ingredients in order of predominance	1,518	21	31,878	1	31,878
701.11—Statement of identity	1,518	24	36,432	1	36,432