for Treatment.'' The purpose of this draft guidance is to assist sponsors in developing drugs for the treatment of low sexual interest, desire, and/or arousal in women. Specifically, this draft guidance addresses FDA's current thinking regarding the overall clinical development program, with a focus on phase 3 trial designs, to support an indication for the treatment of these conditions.

On October 27, 2014, FDA convened a public patient-focused drug development meeting and heard directly from women suffering from female sexual desire and arousal disorders. The following day, FDA held a public scientific workshop with invited experts in sexual medicine to discuss scientific challenges involved in developing drugs to treat these disorders, including diagnostic criteria, endpoints, and patient-reported outcome instruments. Comments from the public and experts that were communicated during these proceedings, as well as comments submitted to FDA through the public docket, were used to inform this draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on developing drugs for the treatment of low sexual interest, desire, and/or arousal in women. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The 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This draft guidance refers to previously approved collections of information found in FDA regulations.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 in 21 CFR part 314 have been approved under OMB Control Number 0910–0001.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25788 Filed 10–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0823]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 (the PRA).

DATES: Fax written comments on the collection of information by November 25, 2016.

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 0910–0340. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Format and Content Requirements for OTC Drug Product Labeling—21 CFR Part 201—OMB Control Number 0910–0340—Extension

In the **Federal Register** of March 17, 1999 (64 FR 13254) (the 1999 labeling final rule), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201). The regulations in part 201 require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Specifically, the 1999 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products.

On June 20, 2000 (65 FR 38191), we published a **Federal Register** final rule that required all OTC drug products marketed under the OTC monograph system to comply with the labeling requirements in § 201.66 by May 16, 2005, or sooner (65 FR 38191 at 38193). Currently marketed OTC drug products are already required to be in compliance with these labeling requirements, and thus will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Modifications of labeling already required to be in Drug Facts format are usual and customary as part of routine redesign practice, and thus do not create additional burden within the meaning of the PRA. Therefore, the burden to comply with the labeling requirements in § 201.66 is a one-time burden applicable only to new OTC drug products introduced to the marketplace under new drug applications (NDAs), abbreviated new drug applications (ANDAs), or an OTC drug monograph, except for products in ''convenience size'' packages.[1] New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on a March 1, 2010, estimate provided by the Consumer Healthcare Products Association (75 FR 49495 at 49496, August 13, 2010), we estimated that approximately 900 new OTC drug product stock-keeping units (SKUs) are introduced to the marketplace each

[1] In a final rule published in the **Federal Register** of April 5, 2002, the Agency delayed the compliance dates for the 1999 labeling final rule for all OTC drug products that: (1) Contain no more than two doses of an OTC drug and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements set forth in § 201.66(d)(1) and (9) and, therefore, qualify for the labeling modifications currently set forth in § 201.66(d)(10) (67 FR 16304 at 16306). The Agency issued this delay in order to develop additional rulemaking for these ''convenience size'' products (December 12, 2006; 71 FR 74474). These products are not currently subject to the requirements of § 201.66. PRA approval for any requirements to which they may be subject in the future will be handled in a separate rulemaking.

year. We estimated that these SKUs are marketed by 300 manufacturers. We estimated that the preparation of labeling for new OTC drug products would require 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is approximately 10,800 hours.

All currently marketed sunscreen products are required to be in compliance with the Drug Facts labeling requirements in § 201.66, and thus will incur no further burden under the information collection provisions in the 1999 labeling final rule. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimate that 60 new SKUs of OTC sunscreen drug products would be marketed each year (77 FR 27230 at 27234). We estimate that these 60 SKUs would be marketed by 20 manufacturers. We estimate that approximately 12 hours would be spent on each label, based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens.

In determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). Since publication of the 1999 labeling final rule, we have received only one request for exemption or deferral. One response over a 10-year period equates to an annual frequency of response equal to 0.1. In the 1999 labeling final rule, we estimated that a request for deferral or exemption would require 24 hours to complete (64 FR 13254 at 13276). We continue to estimate that this type of response will require approximately 24 hours. Multiplying the annual frequency of response (0.1) by the number of hours per response (24) gives a total response time for requesting exemption of deferral equal to 3 hours.

In the **Federal Register** of April 1, 2016 (81 FR 18861), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

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

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

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
201.66(c) and (d) for new OTC drug products	300	3	900	12	10,800
201.66(c) and (d) for new OTC sunscreen products	20	3	60	12	720
201.66(e)	1	0.125	.125	24	3
Total					11,523

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

Dated: October 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25854 Filed 10–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

The Sentinel Post-Licensure Rapid Immunization Safety Monitoring Program; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Thursday, September 1, 2016 (81 FR 60357). The document announced a public workshop entitled ''The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program.'' The document was published with a Web site that changed after the publication of the notice of the workshop. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chris Nguyen, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 4124, Silver Spring, MD 20993–0002; or Cynthia Whitmarsh, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 4122, Silver Spring, MD 20993–0002.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 2016, in FR Doc. 2016–21046, on page 60357, the following correction is made:

On page 60357, in the third column under the **SUPPLEMENTARY INFORMATION** caption, the fifth sentence in the second paragraph is corrected to read ''More information can be found at: *https://www.sentinelsystem.org/vaccines-blood-biologics*.''

Dated: October 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25853 Filed 10–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0730]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

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 November 25, 2016.

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,