

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.
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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.sentinelssystem.org/vaccines-blood-biologics>.”

Dated: October 20, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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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,