

that are broadcast through media such as television, radio, or telephone communications systems must disclose the major risks from the product's package labeling in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the "major statement." If a broadcast advertisement omits the major statement, or if the major statement minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of the FD&C Act, (21 U.S.C. 352(n) and section 201 of the FD&C Act (21 U.S.C. 321(n))), and FDA's implementing regulations at § 202.1(e).

We are revising the information collection to include recommendations found in Agency guidance. The guidance document entitled, "Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer [DTC] Promotional Labeling and Advertisements," provides content and format recommendations for DTC promotional labeling and

advertisements (promotional communications) that present quantitative efficacy and risk information. The guidance document was developed consistent with Agency good guidance practices regulations in 21 CFR 10.115, which provide for comment at any time. The draft guidance document, issued on October 17, 2018, is available at <https://www.fda.gov/media/117573/download> and in docket FDA-2018-D-2613. FDA also maintains a searchable guidance database at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> to facilitate access to these documents.

The guidance document recommends specific content elements pertaining to the presentation of quantitative efficacy and risk information in DTC promotional communications. The guidance also discusses formatting considerations related to the use of visual aids that display quantitative efficacy or risk information in DTC promotional communications. The guidance document explains that the

information collection applies to the third-party disclosure of information pertaining to FDA-regulated products that contain quantitative efficacy or risk information and discusses the Agency's current thinking with regard to this topic.

In the **Federal Register** of October 17, 2018 (83 FR 52484), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received regarding FDA's need for the information, the accuracy of our burden estimate, or ways to minimize burden. Although we are preparing to finalize the guidance document to clarify considerations for quantitative efficacy or risk presentations across various media types and provide additional explanation regarding specific concepts and examples that were included in the draft guidance, none of the revisions pertain to the information collection recommendations discussed in our 60-day notice.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Guidance document recommendations	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
"Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements" as recommended in Section III of the guidance	465	43	19,995	2	39,990

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

According to available data, approximately 465 firms prepare 49,000 FDA-regulated DTC promotional communications annually. Of these communications, we assume 40 percent contain a disclosure of quantitative efficacy or risk information. Based on this information, we calculate that firms each disseminate 43 DTC promotional communications that contain a disclosure of quantitative efficacy or risk information annually. Based on our experience reviewing FDA-regulated promotional communications for drugs, we estimate respondents spend an average of 2 hours to prepare a disclosure as recommended in the guidance. We therefore estimate 19,995 disclosures and a burden of 39,990 hours annually.

Dated: March 26, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Advisory Commission on Childhood Vaccines Meeting; Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** HRSA published a notice in the **Federal Register** on December 20, 2022, concerning 2023 calendar year meetings of the Advisory Commission on Childhood Vaccines (ACCV). The document contained incorrect dates for future meetings. The remaining 2023 ACCV meetings will be held on September 7, 2023, 10:00 a.m. Eastern time (ET)–4:00 p.m. ET and September 8, 2023, 10:00 a.m. ET–4:00 p.m. ET.

**FOR FURTHER INFORMATION CONTACT:** Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs,

HRSA, 5600 Fishers Lane, 08N186B, Rockville, Maryland 20857; (800) 338-2382; or [ACCV@hrsa.gov](mailto:ACCV@hrsa.gov).

**SUPPLEMENTARY INFORMATION:**

**Correction**

In the **Federal Register** of December 20, 2022, FR Doc. 2022-27543, page 77852, column 3, correct the Dates caption to read: "The ACCV meetings will be held on:

- March 1, 2023, 10:00 a.m. Eastern Time (ET)–4:00 p.m. ET;
- March 2, 2023, 10:00 a.m. ET–4:00 p.m. ET;
- September 7, 2023, 10:00 a.m. ET–4:00 p.m. ET;
- September 8, 2023, 10:00 a.m. ET–4:00 p.m. ET."

**Maria G. Button,**

*Director, Executive Secretariat.*

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