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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lea Cranford, Center for Veterinary Medicine (HFV–118), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0615, *lea.cranford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #281 entitled ''Infectious Otitis Externa Drugs for Topical Use in Dogs.'' This draft guidance provides recommendations to help sponsors complete the effectiveness, target animal safety, and labeling technical sections of an NADA for infectious otitis externa drugs for topical use in dogs.

This level 1 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 ''Infectious Otitis Externa Drugs for Topical Use in Dogs.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06380 Filed 3–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2613]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, 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: Submit written comments (including recommendations) on the collection of information by May 1, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0686. 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, 10A–12M, 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.

Prescription Drug Advertising

OMB Control Number 0910–0686—Revision

This information collection supports FDA implementation of Agency regulations and associated guidance. Section 502(n) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(n)) requires that manufacturers, packers, and distributors (firms) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. FDA's prescription drug advertising regulations in § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements

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 [1]

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

[1] 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.

[FR Doc. 2023–06707 Filed 3–30–23; 8:45 am]

BILLING CODE 4164–01–P

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*.

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.

[FR Doc. 2023–06673 Filed 3–30–23; 8:45 am]

BILLING CODE 4165–15–P