

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters "AG", on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197-9000. Note: In no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, it is required that the invoice number or PIN is included; without the invoice number or PIN the payment may not be applied, and the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, SWIFT No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314-418-4013. This phone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's CVM. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53-0196965.

#### B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA

website at <https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm> and scroll down the page until you find the link "Create AGDUFA User Fee Cover Sheet." Select that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Pl., Rockville, MD 20855.

#### C. Product and Sponsor Fees

By December 31, 2021, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2022 using this fee schedule. Fees will be due by January 31, 2022. FDA will issue invoices in November 2022 for any products and sponsors subject to fees for FY 2022 that qualify for fees after the December 2021 billing.

Dated: July 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0363]

#### 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) 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:** Submit written comments (including recommendations) on the collection of information by August 23, 2021.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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—21 CFR Part 202

*OMB Control Number 0910-0686—Extension*

This information collection supports Agency regulations and associated guidance. FDA protects the public health by assuring the safety, effectiveness, and security of a wide range of products. We also help consumers get accurate, science-based information they need to use medicines appropriately and improve their health.

Section 301 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331) prohibits the misbranding of FDA-regulated products, including prescription drugs. Section 502 of the FD&C Act (21 U.S.C. 352) requires that manufacturers, packers, and distributors, or anyone acting on their behalf (firms) include certain information in human prescription drug promotional labeling and advertisements.

Our prescription drug advertising regulations in part 202 (21 CFR part 202) 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).

Section 202.1(e)(6) provides for certain waivers. The waiver request must set forth clearly and concisely the petitioner’s interest in the advertisement, the specific provision of § 202.1(e)(6) from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement is not false, lacking in fair balance or otherwise misleading, or otherwise violative of section 502(n) of the FD&C Act.

Under § 202.1(j)(1), a sponsor must submit advertisements to FDA for prior approval before dissemination if: (1) The sponsor or FDA has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage; (2) FDA has notified the sponsor that the information must be part of the advertisements for the drug; and (3) the sponsor has failed to present to FDA a program for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements, or if such a program has been presented to FDA but is not being followed by the sponsor.

Under § 202.1(j)(1)(iii), a sponsor must provide to FDA a program for assuring that significant new adverse information about the drug that becomes known (*i.e.*, use of drug may cause fatalities or serious damage) will be publicized promptly and adequately to the medical profession in any subsequent advertisements. Under § 202.1(j)(4), a sponsor may voluntarily submit advertisements to FDA for comment prior to publication.

While the regulations establish requirements for prescription drug advertisements, we have developed the

guidance document entitled, “Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements; Guidance for Industry” to clarify requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for human and animal prescription drugs and prescription biological products. The guidance includes recommendations that pertain to traditional print promotional labeling and advertisements (*e.g.*, journal ads, detail aids, brochures), audiovisual promotional labeling (*e.g.*, videos shown in a healthcare provider’s office), broadcast advertisements (*e.g.*, television advertisements, radio advertisements), and electronic and computer-based promotions (*e.g.*, internet, social media, emails, CD-ROMs, DVDs). The guidance document was issued consistent with our Good Guidance Practice regulations in part 10.115 which provide for public comment at any time, and is available from our website at: <https://www.fda.gov/media/87202/download>.

In the **Federal Register** of April 29, 2021 (86 FR 22686), we published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, all generally supportive of FDA’s drug advertising regulations; however, some commenters suggested FDA might do more to promote truthful advertising with regard to prescription drug products. We appreciate all comments. No comment suggested a revision to our current estimate for the information collection.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
<b>CDER Regulated Products:</b>					
202.1(e)(6); waiver request .....	1	1	1	12	12
202.1(j)(1); submission of advertisement .....	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized .....	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA .....	59	1.85	109	20	2,180
<b>CDER Regulated Products:</b>					
202.1(e)(6); waiver request .....	1	1	1	12	12
202.1(j)(1); submission of advertisement .....	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized .....	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA .....	7	2.57	18	20	360
<b>CVM Regulated Products:</b>					
202.1(e)(6); waiver request .....	1	1	1	12	12
202.1(j)(1); submission of advertisement .....	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized .....	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA .....	7	1	7	20	140
<b>Total .....</b>			<b>143</b>		<b>2,758</b>

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

Our estimate of burden we attribute to the reporting provisions in part 202 is based on our experience with the collection and a review of Agency data.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1 2</sup>

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Burden per disclosure	Total hours
202.1; ad prepared in accordance with part 202	670	111.08	74,425	400	29,770,000
202.1(j)(1); info. included re. fatalities or serious damage	1	1	1	40	40
<b>Total</b>			<b>74,426</b>		<b>29,770,040</b>

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

<sup>2</sup> Numbers rounded to the nearest one/one-hundredth.

Under § 202.1, advertisements for human and animal prescription drug and biological products must comply with the standards described in that section. Under § 202.1(j)(1), if information that the use of a

prescription drug may cause fatalities or serious damage has not been widely publicized in the medical literature, a sponsor must include such information in the advertisements for that drug. Based on a review of Agency data we

estimate an average of 29,770,040 hours is incurred annually by respondents in complying with third-party disclosure requirements for prescription drug advertising. We assume a placeholder of 1 for disclosures under § 202.1(j)(1).

TABLE 3—ESTIMATED ANNUAL DISCLOSURE BURDEN DISCUSSED IN AGENCY GUIDANCE

Information collection recommendations	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
Product name placement, size, and prominence in promotional labeling and advertisements' disclosures	715	190.3	136,069	3	408,207

The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and animal prescription drugs are specified in labeling and advertising regulations (§§ 201.10(g) and (h); 202.1(b)–(d)). Based on Agency data, we estimate that, for human and animal prescription drugs and prescription biological products, an average of 715 firms disseminate approximately 136,069 advertisements and promotional pieces each year. We assume that the burden associated with complying with the regulatory requirements discussed in the guidance would be approximately 3 hours per response.

We have adjusted our estimate upward to reflect increases in prescription drug advertisements and associated disclosures.

Dated: July 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–15648 Filed 7–22–21; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2021–N–0387]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Content of Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling and Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities**

**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:** Submit written comments (including recommendations) on the collection of information by August 23, 2021.

**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 numbers for the collections of information are 0910–0856 and 0910–0857. 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](mailto: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.

**I. Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers**

*OMB Control Number 0910–0856—Extension*

This information collection supports the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA’s implementing regulations that govern drug and device labeling and prescription drug and restricted device advertising. Section 502(a) of the FD&C Act (21 U.S.C. 352(a)) specifies that a drug or device shall be deemed to be misbranded if its labeling is false or