4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-D-0500] (formerly Docket No. 2004D-0042)

Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs; Revised Draft Guidance for Industry (Revision 2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reissuance of a revised draft guidance for industry (Revision 2) entitled "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs." We are reissuing the revised draft guidance to incorporate animal prescription drugs. This reissued revised draft guidance, when finalized, will assist manufacturers, packers, and distributors (firms) of human prescription drugs, including biologics, and animal prescription drugs, with meeting the brief summary requirement for prescription drug advertising and the requirement that adequate directions for use be included with promotional labeling for prescription drugs when print materials are directed toward consumers.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this reissued revised draft guidance before it

begins work on the final version of the guidance, submit either electronic or written comments on the reissued revised draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on the proposed collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the reissued revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002; or to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the revised draft guidance document.

Submit electronic comments on the reissued revised draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Regarding human prescription drugs: Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-1200. Regarding human prescription biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring,

MD 20993-0002, 240-402-7911. Regarding animal prescription drugs: Thomas Moskal, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855-2792, 240-402-6251.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the reissuance of a revised draft guidance for industry entitled "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs." We are reissuing the revised draft guidance to incorporate animal prescription drugs; there are no other revisions to the revised draft guidance for industry issued February 9, 2015 (80 FR 6998).

As stated previously, the revised draft guidance updates prior FDA policy and describes the Agency's current thinking regarding the brief summary requirement for consumer-directed print prescription drug advertisements. Specifically, the revised draft guidance includes recommendations for developing a consumer brief summary and notes that, so long as firms include appropriate information in a print advertisement as outlined in the revised draft guidance, FDA does not intend to object for a failure to include certain other information.

Additionally, the revised draft guidance provides new recommendations regarding the adequate directions for use requirement for consumer-directed print promotional labeling for prescription drug products. Although the requirement in 21 CFR 201.100(d) and 21 CFR 201.105(d) for firms to provide adequate information for use is generally fulfilled by providing the full FDA-approved package insert (PI), the revised draft guidance provides that, in exercising its enforcement discretion, FDA does not intend to object for failure to include the full PI with consumer-directed print promotional labeling pieces if firms include the appropriate information

as outlined in the revised draft guidance, i.e., the same information in the consumer brief summary. This recommendation is designed to standardize the information consumers receive in print prescription drug product advertisements and promotional labeling and to make information more understandable to consumers.

FDA issued a draft guidance in the Federal Register of February 10, 2004 (69 FR 6308), entitled "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements." FDA requested comments on whether the draft guidance provided sufficient guidance on the content of the consumer brief summary and also requested research results on potential formats for the consumer brief summary. Comments, suggestions, and research were submitted to Docket No. 2004D-0042 and were carefully analyzed and considered before developing the revised draft guidance.

FDA issued the revised draft guidance in the Federal Register of February 9, 2015, giving interested parties an opportunity to submit comments by May 11, 2015. We are reissuing the revised draft guidance to incorporate animal prescription drugs; there are no other revisions to the revised draft guidance issued February 2015.

The revised draft guidance incorporates information from recent social science research, clarifies the risk information that should be included in the consumer brief summary, and recommends several formatting options for this information. The revised draft guidance also recommends the use of consumer-friendly language and visual techniques to improve accessibility for consumers. Additionally, the revised draft guidance recommends that firms not disseminate the full PI to fulfill the requirements in § 201.100(d) for consumer-directed print promotional labeling for prescription drugs. Rather, the revised draft guidance recommends that

firms provide the same content and format created for the consumer brief summary. FDA is issuing the revised guidance as a draft to allow for public comment on the recommendations.

The reissued revised draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The reissued revised draft guidance, when finalized, will represent FDA's current thinking on the brief summary and adequate directions for use requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document. The revised draft guidance also refers to previously approved collection of information found in FDA regulations.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors (firms) of human and animal prescription drug products, including biological products for use in humans.

Burden Estimate: The reissued revised draft guidance pertains to the brief summary requirement for prescription drug advertising and the requirement that adequate directions for use be included with promotional labeling for human and animal prescription drugs when print materials are directed toward consumers.

The reissued revised draft guidance, in part, explains FDA's current policy position that FDA does not intend to object for failure to include the entire PI to fulfill the requirements of §§ 201.100(d) and 201.105(d)(1) for promotional labeling pieces directed toward consumers, if firms instead provide information on the most serious and the most common risks associated with the product, while omitting less important information. Specifically, FDA recommends that any Boxed Warning, all Contraindications, certain information regarding Warnings and Precautions (i.e., the most clinically significant information from the Warnings and Precautions section of the PI, information that would affect a decision to prescribe or take a drug, monitoring or laboratory tests that may be needed, special precautions not set forth in other parts of the PI,

and measures that can be taken to prevent or mitigate harm), and the most frequently occurring Adverse Reactions should be included.

Furthermore, FDA recommends that information should include the indication for the use being promoted. Information regarding patient directives (such as "discuss with your health care provider any pre-existing conditions" or "tell your health care provider if you are taking any medications") should also be included. Other types of information may be included if relevant to the drug or specific indication referred to in the promotional material(s). A statement should be included that more comprehensive information can be obtained from various sources, including the firm.

Thus, the reissued revised draft guidance recommends that firms disclose certain information to others in place of the PI to fulfill the requirements in §§ 201.100(d) and 201.105(d). This "third-party disclosure" constitutes a "collection of information" under the PRA.

FDA estimates that approximately 400 firms subject to § 201.100(d) disseminate 24,000 consumer-directed print promotional labeling pieces annually. FDA estimates that approximately 40 firms subject to § 201.105(d) disseminate 2,000 consumer-directed print promotional labeling pieces annually. FDA estimates that it will take firms approximately 10 hours to compile and draft the information needed to provide the information recommended in the revised draft guidance. Please note that the requirements related to print advertising pieces and the associated burden is already accounted for under the requirements under 21 CFR 202.1 and its approved information collection OMB control number 0910-0686 and, therefore, is not included in the burden estimate reported in table 1.

Table 1.--Estimated Annual Reporting Burden[1]

Adequate Information for Use: Disclosing Risk Information in Consumer-Directed Promotional Labeling	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Hours per Disclosure	Total Hours
Disclosures Related to Adequate Information for Use (§ 201.100(d))	400	60	24,000	10	240,000
Disclosures Related to Adequate Information for Use (§ 201.105(d))	40	50	2,000	10	20,000

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

This reissued revised draft guidance also refers to previously approved collections of information found in FDA regulations with respect to the brief summary requirement for print advertisements. These collections of information are subject to review by OMB under the PRA. The collection of information in § 202.1 has been approved under OMB control number 0910-0686.

III. Comments

In addition to general comments, FDA specifically requests comments on the following issues:

- In the revised draft guidance, FDA provides recommendations regarding the content and format of the consumer brief summary. Is this the most useful information for consumers to use in determining whether to take a medication or seek more information about a product, and if not, what information would be more useful?
- FDA is also interested in relevant research that has been conducted or alternative formats that were developed after we received comments on the 2004 draft guidance.
- In the revised draft guidance, FDA suggests that the adequate directions for use requirement be fulfilled by providing the consumer brief summary rather than the full PI for the product. FDA seeks comments regarding this recommendation.

Persons who commented on the version of the revised draft guidance issued in February 2015 do not need to resubmit their comments. When finalizing the revised draft guidance, we will review comments received on this reissued version, as well as the version issued February 2015.

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, or http://www.regulations.gov.

Dated: July 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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