



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-4079]

Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements;  
Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.” The guidance clarifies the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for human prescription drugs, including prescription biological products, and for animal prescription drugs. This guidance finalizes the revised draft guidance issued on November 20, 2013 (“Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling”).

FDA is also 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 (the PRA).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira\_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title “Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.” Also, include the FDA docket number found in brackets in the heading of this document.

You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-1999-D-4079 for “Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements; Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the 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.gpo.gov/fdsys/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.

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 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; or 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 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 requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding human prescription drugs:* Sheila Ryan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3320, 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 (HFV-216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6251.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.” This guidance clarifies the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for human prescription drugs, including prescription biological products, and for animal prescription drugs. The disclosure of the product name in promotional labeling and advertisements for all human prescription drugs, including prescription biological products, and animal prescription drugs is important for the proper identification of such products to ensure their safe and effective use.

The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and for prescription animal drugs are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h) and 202.1(b), (c), and (d)).

The recommendations in this guidance pertain to product names in traditional print promotional labeling and advertisements (e.g., journal ads, detail aids, brochures), audiovisual promotional labeling (e.g., videos shown in a health care 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).

In the *Federal Register* of November 20, 2013 (78 FR 69691), FDA announced the availability of the revised draft guidance entitled “Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.” FDA received one comment on the revised draft guidance, which requested additional clarification on the individual recommendations in the guidance, and FDA considered this comment as the guidance was finalized. In addition to a title change and editorial changes made primarily for clarification, the guidance has been revised to clarify certain concepts discussed in the revised draft guidance and to provide examples illustrating prominence issues.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.” 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. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. The information collection requests in support of the guidance are discussed below. Specifically, the guidance discusses the

requirement in FDA's regulations for prescription drug promotional labeling and advertisements to include the established name in conjunction with the proprietary name, and explains FDA recommendations that:

- Firms should include the established name at least once per page or spread where the proprietary name most prominently appears.
- The established name should be placed either directly beside or below the proprietary name without any intervening matter.
- The size of the established name should be at least half the size of the presentation of the proprietary name wherever the established name is required.
- For superimposed text that is equivalent to a headline or tagline, the established name should be presented alongside the most prominent presentation of the proprietary name in audiovisual promotional materials (promotional labeling and broadcast advertisements).
- For electronic and computer-based promotion, the established name should accompany the proprietary name at least once per web page, and this should generally be where the proprietary name most prominently appears on the web page.

Thus, the guidance recommends that firms disclose certain information to others to fulfill the product name placement requirements found in FDA's regulations. This "third-party disclosure" constitutes a "collection of information" under the PRA. Disclosures in advertising pursuant to 21 CFR 202.1 are covered by an existing information collection (OMB control number 0910-0686), so this information collection request covers only disclosures in labeling in accordance with 21 CFR 201.10(g) and (h).

In the *Federal Register* of November 20, 2013, FDA published a 60-day notice

requesting public comment on the proposed collection of information and the estimated annual burden for third party disclosure. FDA received no comments in response to the four information collection topics solicited in the notice. FDA has received more up-to-date submission data since the 60-day notice published, therefore, we have adjusted our estimates of respondents and disclosures accordingly. The estimated amount of time per disclosure has not changed. We therefore estimate the burden associated with the information collection as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Guidance Recommendations	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours
Disclosures Related to Product Name Placement, Size, and Prominence	407	256.4	104,358	3	313,074

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

As reflected in table 1, we provide an estimate of the annual third-party disclosure burden associated with this collection of information. 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 (21 CFR 201.10(g) and (h); 202.1(b), (c) and (d); and 610.62). Using calendar year 2015 data, FDA estimates that, for prescription human and animal drugs and biological products, approximately 407 firms disseminate approximately 104,358 advertisements and promotional pieces each year. We further estimate that the burden hours associated with the regulatory requirements would be approximately 3 hours per disclosure.

FDA is issuing this final guidance subject to OMB approval of the information collection. Before implementing the information collection provisions of the guidance, FDA will publish a

notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the collections of information, including OMB control number(s) for newly approved collections.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information associated with 21 CFR 202.1 have been approved under OMB control number 0910-0686.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <https://www.regulations.gov>.

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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