

4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document

**FOR FURTHER INFORMATION CONTACT:** Melissa Reisman, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of July 2, 2013 (78 FR 39736), FDA published a notice announcing the availability of a draft guidance document entitled "Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products." The notice invited comments on the draft guidance by November 22, 2013.

We are extending the comment period for the draft guidance to May 9, 2014. We are taking this action to allow interested persons additional time to submit comments and to allow for public discussion at the April 10-11, 2014, Cellular, Tissue, and Gene Therapies Advisory Committee meeting, where FDA will present the draft guidance document for review.

The Agency believes that this extension will not significantly delay further FDA action on this guidance.

**II. Request for Comments**

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>.

Dated: November 14, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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

**Draft Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling." When finalized, the draft guidance will replace the guidance of the same title issued January 25, 2012. The draft guidance clarifies the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human drugs, including biological drug products, and prescription animal drugs and articulates the circumstances under which FDA intends to exercise enforcement discretion.

**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 comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 21, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; or the Communications Staff (HFV-12), 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 draft guidance document.

Submit electronic comments on the 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:* Cynthia Ng, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3278, Silver Spring, MD 20993-0002, 301-796-1200.

*Regarding prescription human biological products:* Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

*Regarding animal prescription drugs:* Julie Garnier, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6878.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling." In the **Federal Register** of January 25, 2012 (77 FR 3779), FDA announced the availability of a guidance entitled "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling." The 2012 guidance discusses the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human and animal drugs and biological products. The draft guidance clarifies these requirements and articulates the circumstances under which FDA intends to exercise enforcement discretion.

The disclosure of the product name in promotional labeling and advertising for all prescription human and animal drug and biological products is important for the proper identification of such products to ensure their safe and effective use.

The placement, size, prominence, and frequency of proprietary and established names for human and animal prescription drug products are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h); 202.1(b), (c), and (d)). These regulations are also applicable to biological product labeling and advertising materials.

The recommendations in the draft guidance pertain to product names in traditional print media promotion (e.g., journal ads, detail aids, brochures), audiovisual promotional labeling (e.g.,

videos shown in a health care provider's office), broadcast media promotion (e.g., television advertisements, radio advertisements), and electronic and computer-based promotional labeling and advertisements such as Internet promotion, social media, emails, CD-ROMs, and DVDs.

Following issuance of the guidance in 2012, FDA recognized the need for additional clarification and explanation of how FDA would exercise its enforcement discretion.

This draft guidance updates the 2012 guidance as follows:

- Clarifies issues about intervening matter in relation to the juxtaposition of the proprietary and established name;
- States that FDA intends to exercise enforcement discretion regarding the requirements surrounding the use of the established name on pages or spreads and offers an example of what is expected;
- Clarifies the requirements regarding the use of proprietary names in the running text;
- States that FDA intends to exercise enforcement discretion regarding the established name's presentation in columns;
- Removes the recommendation that the established name be included in the audio portion of an audiovisual promotion; and
- Clarifies issues relating to the established name's presentation on Web pages or electronic screens.

This 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 Agency's current thinking on product name placement, size, and prominence in advertising and promotional labeling. 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. 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 that 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** for 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.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in § 202.1 have been approved under OMB control number 0910–0686.

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 to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.

*Description of Respondents:* Respondents to this collection of information are manufacturers and distributors (firms) of prescription human drug products, including

biological drug products, and prescription animal drug products.

*Burden Estimate:* The draft guidance pertains to the requirement for prescription drug advertising and promotional labeling to include the established name in conjunction with the proprietary name.

The draft guidance, in part, explains FDA's current policy as follows:

- 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.
- For electronic and computer-based promotion, the established name should accompany the proprietary name at least once per Web page or screen, and this should generally be where the proprietary name most prominently appears on the Web page or screen.

Thus, the draft guidance recommends that firms disclose certain information to others when fulfilling the product name placement requirements. This "third-party disclosure" constitutes a "collection of information" under the PRA.

FDA estimates that approximately 400 firms disseminate approximately 82,100 advertisements and promotional pieces each year. FDA estimates that it will take firms approximately 3 hours to compile and draft the information needed to fulfill the product name placement, size, and prominence requirement in advertising and promotional labeling.

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

Product name placement, size, and prominence in advertising and promotional labeling	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Submissions Related to Product Name Placement, Size, and Prominence .....	400	205	82,100	3	246,300

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

### III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. 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/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/Guidance/ComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: November 14, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-1358]

#### Draft Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation" dated November 2013. The draft guidance document provides recommendations to submitters and FDA reviewers in preparing and reviewing 510(k) submissions for nucleic acid-based HLA

test kits used for matching of donors and recipients in transfusion and transplantation. The guidance provides detailed information on the types of studies FDA recommends for validation of HLA test kits submitted as 510(k)s.

**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 comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 18, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the 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:** John Reilly, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation" dated November 2013.

The draft guidance provides recommendations to submitters and FDA reviewers in preparing and reviewing 510(k) submissions for nucleic acid-based HLA test kits used for the matching of donors and recipients in transfusion and transplantation, whether testing is for a single locus or for multiple loci simultaneously. This includes detailed information on the types of studies FDA recommends for validation of HLA test

kits submitted as 510(k)s. The guidance document addresses the types of studies and other information that FDA recommends be used in designing and conducting studies for validation of nucleic acid-based HLA test kits and preparing a 510(k) submission.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

##### II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 have been approved under OMB control numbers 0910-0078 and 0910-0582; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 56 have been approved under OMB control number 0910-0130; and the collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0586.

##### III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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>.