

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0319]

Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled "Dear Health Care Provider Letters: Improving Communication of Important Safety Information." This guidance offers specific recommendations to industry on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. This guidance provides recommendations on when to use a DHCP letter, the types of information to include in the DHCP letter, how to organize the information so that it is communicated effectively to health care providers, and formatting techniques to make the information more accessible. This guidance finalizes the draft guidance issued in November 2010.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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. 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.

Submit electronic comments on the 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: Lori A. Bickel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6353, Silver Spring, MD 20993, 301-796-0210; or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Dear Health Care Provider Letters: Improving Communication of Important Safety Information." This document offers specific guidance to industry and FDA staff on the content and format of DHCP letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. This guidance gives specific instruction on what should and should not be included in DHCP letters. To date, some DHCP letters have been too long, have contained promotional material, or

otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes advice on consulting with FDA to develop a DHCP letter, when to send a letter, what type of letter to send, and conducting an assessment of the letter's impact.

In the Federal Register of November 12, 2010 (75 FR 69449), FDA announced the availability of a draft guidance for industry and FDA staff entitled "Dear Health Care Provider Letters: Improving Communication of Important Safety Information." The notice gave interested persons an opportunity to comment by January 11, 2011. The Agency received several comments from health care providers, firms, and other groups. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified information in the guidance in response to the comments or on our own initiative. This guidance finalizes the draft guidance issued in November 2010.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Dear Health Care Provider Letters: Improving Communication of Important Safety Information." 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

This guidance contains information collection provisions that 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 this guidance were approved under OMB control number 0910-0754.

III. 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>.

IV. Electronic Access

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

Dated: January 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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