

FDA Publishes New Guidance on Letters from Manufacturers to Health Care Providers

Written by Paul T. Kim

January 29, 2014

The Food and Drug Administration (FDA) issued a new guidance document on Dear Health Care Provider (DHCP) letters, titled “Dear Health Care Provider Letters: Improving Communication of Important Safety Information.” DHCP letters are correspondence from a manufacturer or distributor to health care providers containing new or updated information regarding a human drug or biologic. These letters have become more commonly delivered electronically via email and online postings rather than a physical post. The guidance provides recommendations on--

1. when to issue a DHCP letter;
2. what type of information should be included in the letter;
3. how to organize that information so that it is communicated effectively to health care providers; and
4. which formatting techniques make the information more accessible.

The guidance fleshes out the circumstances that require the issuance of one of three types of DHCP letters described in FDA regulations (21 CFR 200.5). The guidance also provides a model letter for each of the three types of letters described in the regulations, as well as the appropriate content and format. This table summarizes the three types of DHCP letters, and the recommended use, content, and format for each one.

In addition to providing detailed guidance on the content that should be included, FDA instructed that a DHCP letter should be limited to two pages and should not include detail or other information that would divert attention from the more important information. The guidance provides the following examples of unnecessary information: market information about the drug, extensive details about the design of a clinical study, information about a safety review panel, plans to investigate the problem (if not specifically related to safety), and promotional language or claims.

RELATED INDUSTRIES

- [Healthcare](#)
- [Life Sciences](#)

This communication is intended for general information purposes and as a service to clients and friends of Foley Hoag LLP. This communication should not be construed as legal advice or a legal opinion on any specific facts or circumstances, and does not create an attorney-client relationship.

United States Treasury Regulations require us to disclose the following: Any tax advice included in this document was not intended or written to be used, and it cannot be used, for the purpose of avoiding penalties under the Internal Revenue Code.

Attorney advertising. Prior results do not guarantee a similar outcome. © 2017 Foley Hoag LLP. All rights reserved.