

New FDA Guidance Documents Available

The U.S. Food and Drug Administration (FDA) has announced the availability of two new guidance documents: “Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act” and “Guidance for Industry: Labeling OTC Human Drug Products--Questions and Answers”.

“Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act”

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. This guidance describes the amount, type, and quality of evidence that the FDA recommends a manufacturer have to substantiate a claim under this section of the Federal Food, Drug, and Cosmetic Act. It is limited to issues pertaining to substantiation under section 403(r)(6) and does not extend to substantiation issues that may exist in other sections of the Act.

[Guidance for Industry-Substantiation for Dietary Supplement Claims](#)

“Guidance for Industry: Labeling OTC Human Drug Products--Questions and Answers”

This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products in complying with the agency's regulation on standardized content and format requirements for the labeling of OTC drug products. This guidance primarily discusses labeling questions that have been frequently asked by manufacturers, packers, and distributors relating to these requirements. The labeling examples in this guidance show various format and content features and suggest how OTC drug monograph labeling information finalized before the new requirements can be converted to the new format. This guidance finalizes the draft guidance of the same name published January 13, 2005 (70 FR 2415).

[Guidance for Industry-Labeling OTC Human Drug Products-Questions and Answers](#)

FDA guidance documents, including the two discussed in this article, do not establish legally enforceable responsibilities. Instead, guidances describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidances means that something is suggested or recommended, but not required.

Written and electronic comments on FDA guidances can be submitted at any time. Written comments should be addressed as follows: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Electronic comments or submissions will be accepted by FDA only through the Federal Dockets Management System at <http://www.regulations.gov>.

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