
The Food and Drug Administration (FDA) broadly defines a dietary supplement as a “a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients” (1). Since the early 1990s, the use of dietary supplements has been on the rise, and the Centers for Disease Control and Prevention (CDC) estimates that 40% of Americans currently use some form of these products (2).

After the passage of the Dietary Supplementation Health and Education Act of 1994, the responsibility for establishing the safety of a dietary supplement was shifted. In an effort to meet the demands of the growing number of American consumers of supplements, the FDA accepted the immense responsibility of determining whether use of a new product was hazardous, rather than requiring manufacturers to scientifically establish the safety of their product before use. The Institute of Medicine and the National Research Council of the National Academies assisted the FDA in this process by creating a framework within which this responsibility could be fulfilled. In Dietary Supplements: A Framework for Evaluating Safety, this framework and the comprehensive process by which it was created are clearly outlined. This 506-page hardcover book begins with an excellent 18-page executive summary that provides a clear synopsis of the entire framework development. In-depth information about the development process can be found in the subsequent 13 chapters, which further break down the review process into individual steps. The first 2 chapters provide background information about the previous regulation of dietary supplements, and chapter 3 outlines the framework itself. Chapters 4, 5, 6, and 7 examine the relevance of various categories of scientific evidence: human information and data, animal data, information about related substances, and in vitro data, respectively. Each of these 4 chapters opens with a guiding principle taken from the framework, which is followed by an in-depth discussion of the usefulness of each subset of information.

Chapters 8 and 9 discuss interactions and vulnerable groups, respectively; this information must also be considered during the safety determination process. Chapters 10, 11, and 12 discuss the use of the framework: how data are integrated; how the framework is applied; and what factors influence the use of the framework. Finally, findings and recommendations are discussed in chapter 13. Additional background information and examples of framework applications that further elucidate the framework process can be found in the almost 200-page appendix. Overall, this book provides readers with a detailed, straightforward discussion of the FDA framework for evaluating dietary supplements and will be a useful resource as the framework is put into practice.

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REFERENCES