



Approximate study time: 1 hour



Level: Introductory



Audience: Sales and marketing, regulatory affairs, and legal personnel



Category: Sales and marketing



Region: USA



CPD Points: 1



Module outline

- Regulation of advertising and promotion of drugs
- Classifying promotional communications
- Advertisements and promotional labeling
- Statutory and regulatory requirements
- Types of advertisement
- Misbranding and distribution of an unapproved drug
- FDA offices
- FDA advisory and enforcement actions
- Civil litigation by competitor
- Submission of communication materials to FDA
- FDA's Bad Ad Program
- Compliance programs and OIG enforcement
- Provision of samples
- Assessment

Advertisements and promotional labeling of prescription drugs in the USA must comply with statutory and regulatory requirements.

Advertising and promotion are also subject to guidance from the Food and Drug Administration (FDA) and from industry and professional codes of practice. By identifying the requirements and summarizing the extensive guidance that applies, this course and its companions will help you to advertise and promote your products without incurring legal or regulatory sanctions.

In this course we set out the legal framework for the regulation of advertising and promotion of prescription drugs in the USA. We identify the regulatory authorities and sources of guidance. We summarize basic requirements that advertisements and promotional labeling must meet, and we identify consequences that may follow failure to comply.

In companion courses, we deal with regulatory compliance in general, with considerations that are particular to consumer-directed advertising and online promotion, and with certain interactions with healthcare professionals.



Who will benefit from this module?

Sales and marketing personnel need to understand the legal and regulatory requirements that must be met when advertising and promoting prescription drugs in the USA. In addition, this module will be of particular benefit to regulatory affairs and legal personnel involved with aspects of marketing.



Learning objectives

- Identify the federal laws and regulatory authorities that govern advertising and promotion of prescription drugs in the USA
- Identify sources of guidance on such advertising and promotion
- Distinguish various types of promotional communication
- Discuss the distinction between advertisement and promotional labeling
- Specify statutory and regulatory requirements that must be met by promotional communications that make product claims
- Distinguish various types of advertisement
- Outline the activities of the offices of the Food and Drug Administration (FDA) that oversee compliance with requirements on advertising and promotion
- Identify advisory and enforcement actions by the FDA, and other consequences of violations of federal law
- Specify requirements for submission of promotional materials to the FDA
- Outline the role of the Office of Inspector General and its compliance program guidance

