



Approximate study time: 1.5 hours



Level: Introductory/Intermediate



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



Category: Sales and marketing



Region: USA



CPD Points: 1.5



Module outline

- Common drug advertising and promotion issues
- Relate brand and established names
- Frequency of presentation of established name
- Be consistent with the prescribing information (PI)
- Information possibly consistent with the PI
- Information not consistent with the PI
- Include only substantiated information
- Be truthful and not misleading, reveal material facts, and provide fair balance
- Include information on risks
- Balance risks and effectiveness
- Reveal other material information
- Avoid selective presentation of favorable information
- Endorsements and testimonials
- Avoid broadening or inadequate representation of indications
- Use up-to-date information
- Use statistics carefully
- Avoid misleading juxtaposition of information
- Avoid misbranding of an investigational drug
- Brief summary and adequate information for use in print media
- Major statement in broadcast ads
- Make adequate provision for access to product labeling
- Treat comparative claims with care
- Comparisons of price, dosing, and indications
- FDA examples of violative and non-violative ads
- 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 explain how to advertise and promote prescription drugs in various media, whether to healthcare professionals or consumers, in compliance with legal requirements and guidance from the FDA.

In companion courses, we set out the legal framework for regulation, and we deal with considerations that are particular to consumer-directed advertising and online promotion and to 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 benefit to regulatory affairs and legal personnel involved with aspects of marketing.



Learning objectives

- Identify common issues with drug advertising and promotion
- Specify regulatory requirements for the presentation of brand and non-proprietary names of drugs
- Emphasize the importance of consistency with prescribing information, and give examples of types of information that are, and types that are not, consistent
- Describe how to support claims for products in promotional communications
- Be truthful and not misleading, reveal material facts, and provide fair balance between effectiveness and risks in promotional communications
- Avoid the pitfalls of: selective presentation of favorable information, broadening or inadequate representation of indications, use of out-of-date information, misuse of statistics, misleading juxtaposition of information, and misbranding of an investigational drug
- Deal appropriately with endorsements and testimonials
- Outline the role of the brief summary and adequate information for use in print advertisements and promotional labeling
- Outline the role of the major statement, and make adequate provision for access to product labeling, in broadcast advertisements
- Treat comparative claims with care
- Make comparative promotional claims regarding price, dosing, and indications