

## Handout

### Selected FDA Guidance Documents

Drug Advertising: Glossary of Terms [www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms](http://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms)

Prescribing Information Resources for Industry

[www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources](http://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources)

Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements.

[www.fda.gov/files/drugs/published/Labeling-for-Human-Prescription-Drug-and-Biological-Products---Implementing-the-PLR-Content-and-Format-Requirements.pdf](http://www.fda.gov/files/drugs/published/Labeling-for-Human-Prescription-Drug-and-Biological-Products---Implementing-the-PLR-Content-and-Format-Requirements.pdf)

FDA Department of Health and Human Services- Subchapter C- Drugs: General; Part 201- Labeling

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201)

[Patient Labeling Resources For Industry](#)

[www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources](http://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources)

Patient Medication Information (PMI)

[www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-medication-information-pmi](http://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-medication-information-pmi)

[www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/cm072392.pdf](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/cm072392.pdf)

FDA PI website: <https://www.accessdata.fda.gov/scripts/cder/daf/>

Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs [www.fda.gov/media/70768/download](http://www.fda.gov/media/70768/download)

Labeling Requirements –Misbranding Sections 502(a) and 201(n)

[www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding#:~:text=Section%20502\(a\)%20declares%20that,or%20misleading%20in%20any%20particular](http://www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding#:~:text=Section%20502(a)%20declares%20that,or%20misleading%20in%20any%20particular)

Presenting Risk Information in Prescription Drug and Medical Device Promotion. [www.fda.gov/media/76269/download](http://www.fda.gov/media/76269/download)

Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products. Questions and Answers Guidance for Industry. [www.fda.gov/media/173172/download](http://www.fda.gov/media/173172/download)

[www.fda.gov/drugs/prescription-drug-advertising/product-claim-ad-correct](http://www.fda.gov/drugs/prescription-drug-advertising/product-claim-ad-correct)

[www.fda.gov/drugs/prescription-drug-advertising/reminder-ad-correct](http://www.fda.gov/drugs/prescription-drug-advertising/reminder-ad-correct)

[www.fda.gov/drugs/prescription-drug-advertising/correct-help-seeking-ad](http://www.fda.gov/drugs/prescription-drug-advertising/correct-help-seeking-ad)

Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format Final Rule, Questions and Answers.

[www.fda.gov/media/175074/download](http://www.fda.gov/media/175074/download)

Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices.

[www.fda.gov/media/88545/download](http://www.fda.gov/media/88545/download)

Guidance for Industry Internet/Social Media Platforms with Character Space Limitations. [www.fda.gov/media/88551/download](http://www.fda.gov/media/88551/download)

For Industry: Using Social Media [www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/industry-using-social-media](http://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/industry-using-social-media)

Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers

[www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses)

Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers

[www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-and-device-manufacturer-communications-payors-formulary-committees-and-similar-entities](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-and-device-manufacturer-communications-payors-formulary-committees-and-similar-entities)

Labeling Requirements – Misbranding

[www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding](http://www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding)

Mislabeling vs. Misbranding: A Practical Guide with Examples February 22, 2023 [www.thelangelfirm.com/debt-collection-defense-blog/2023/february/mislabeling-vs-misbranding-a-practical-guide-wit/](http://www.thelangelfirm.com/debt-collection-defense-blog/2023/february/mislabeling-vs-misbranding-a-practical-guide-wit/)

The Office of Prescription Drug Promotion (OPDP) [www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp](http://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp)

[OPDP Regulatory Information and Guidance Documents. www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/opdp-regulatory-information#Guidances](http://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/opdp-regulatory-information#Guidances)

Warning Letters. [www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters](http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

QSYMIA FDA Warning Letter Example. [www.fda.gov/media/126604/download](http://www.fda.gov/media/126604/download); [www.fda.gov/media/126605/download](http://www.fda.gov/media/126605/download)

FDA's 'Bad Ad' Program Encourages HCPs to Report False or Misleading Prescription Drug Promotion. [www.fda.gov/drugs/office-prescription-drug-promotion/fdas-bad-ad-program-encourages-hcps-report-false-or-misleading-prescription-drug-promotion#:~:text=The%20FDA%20%20%20Bad%20Ad%20Program&text=The%20program%20encourages%20HCPs%20to,to%20BadAd%40fda.gov](http://www.fda.gov/drugs/office-prescription-drug-promotion/fdas-bad-ad-program-encourages-hcps-report-false-or-misleading-prescription-drug-promotion#:~:text=The%20FDA%20%20%20Bad%20Ad%20Program&text=The%20program%20encourages%20HCPs%20to,to%20BadAd%40fda.gov)

PhRMA Code: Interactions with Healthcare Professionals.

[phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code---Final.pdf](http://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code---Final.pdf)

Presenting Risk Information in Prescription Drug and Medical Device Promotion. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/presenting-risk-information-prescription-drug-and-medical-device-promotion>

Consumer-Directed Broadcast Advertisements <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/consumer-directed-broadcast-advertisements>

Direct-to-Consumer Prescription Drug Advertisements: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/direct-consumer-prescription-drug-advertisements-presentation-major-statement-clear-conspicuous>