DIA

# Key Advertising and Promotion FDA Guidances

**Hear directly from FDA by attending the session "FDA Draft Guidance and Initiatives" at the Ad Promo Regulatory Affairs Conference.**

## DIRECT-TO-CONSUMER

- Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs (REVISED DRAFT)
- Consumer-Directed Broadcast Advertisements (FINAL GUIDANCE)
- Direct-to-Consumer Television Advertisements - FDAAA DTC Television Ad Pre-Dissemination Review Program (DRAFT GUIDANCE)

## MEDICAL

- Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products - Recommended Practices (DRAFT GUIDANCE)
- Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices (REVISED DRAFT)
- Industry-Supported Scientific and Educational Activities (FINAL GUIDANCE)
- Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (DRAFT GUIDANCE)

## SUBMISSIONS

- Fulfilling Regulatory Requirements for Post-Marketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (DRAFT GUIDANCE)
- Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs (DRAFT GUIDANCE)

## SOCIAL MEDIA

- Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (DRAFT GUIDANCE)
- Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (DRAFT GUIDANCE)

## MISCELLANEOUS

- Presenting Risk Information in Prescription Drug and Medical Device Promotion (DRAFT GUIDANCE)
- *2017 Release* Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling (FINAL GUIDANCE)
- *2017 Release* Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities (DRAFT GUIDANCE)
- *2017 Release* Medical Product Communications That Are Consistent with the FDA-Required Labeling (DRAFT GUIDANCE)

*Please note some of these guidances are final but the majority of them are in draft state. FDA states, "Draft regulations and guidances are documents that have been proposed, but FDA has not made a decision as to whether the proposal will be adopted in whole, in part, or not at all.

Source: FDA Guidance Documents. https://www.fda.gov/RegulatoryInformation/Guidances/