Guiding Your Company to Success: Itemization of FDA Guidances Regarding Drug and Medical Devices

I. What are FDA Guidances and How Can You Benefit From Knowing More?

The FDA has taken steps in an effort to guide pharmaceutical companies in how they label, promote, advertise, and conduct risk management of their products. It drafts guidance documents which represent the Agency's current thinking on particular areas concerning a wide range of products including drugs and medical devices. While these guidance documents do not bind the FDA, they do suggest to companies what the FDA believes is the appropriate action in the above areas. The FDA contends that a company does not necessarily have to comply with these guidances so long as their chosen approach meets the applicable statutory or regulatory requirements.

While the FDA states that these guidances do not create or confer any rights, since they also do not bind the FDA, it is prudent for any pharmaceutical company to be aware of guidances affecting any of its products or operations. While FDA guidances do not have the force of law, they may, if followed, allow pharmaceutical companies to demonstrate a commitment to patient and product safety.

A detailed summary of all final and draft guidances may be found on the Agency's website, *www.fda.gov*. Simply click on the "G" tab, and under the *Guidance Section* will be separate sections dedicated to drug and medical device guidances. Guidance documents may also be found through the Division of Drug Information, also located at *www.fda.gov.*

II. FDA Guidances Regarding Labeling, Advertising, Promotional Material, and Risk Management

This section provides a sampling of current guidances in the areas of labeling, advertising, promotional material, and risk management.[1] A detailed summary of all available guidances may be found on the Agency's website, *www.fda.gov.*

A. Labeling:

i. *Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products* (Final)
ii. *Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products* (Draft)
iii. *Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products* (Final)
iv. *Content and Format for Geriatric Labeling* (Final)
v. *Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products* (Draft)
vi. *Contents of a Complete Submission for the Evaluation of Proprietary Names* (Draft)
vii. *Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims* (Draft)
viii. *Labeling for Combined Oral Contraceptives* (Draft)
ix. *Labeling for Human Prescription Drugs – Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information* (Final)
x. *Labeling for Human Prescription Drug and Biological Products – Implementing the New Content and Format Requirements* (Draft)
xi. *Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)* (Draft)
xii. *Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Recommended Prescribing Information for Health Care Providers and Patient Labeling* (Draft)
xiii. *Public Availability of Labeling Changes in "Changes Being Affected" Supplements* (Draft)
xiv. *Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications* (Draft)
xv. *Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices* (Final)
xvi. *Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products* (Draft)
xvii. *Presenting Risk Information in Prescription Drug and Medical Device Promotion*
xviii. *Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devises Intended for Professional Use*
xix. *Conspicuous Mark of Manufacturers on Single-Use Devices*
xx. *User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide*
xxi. *Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA*
xxii. *Labeling for Electronic Anti-Theft Systems*
xxiii. *Alternative to Certain Prescription Device Labeling Requirements*
xxiv. *Warning Labels for Dye and Multiple Wavelength Lasers* (Laser Notice 16)
xxv. *Optional Interlocks – Labeling* (Laser Notice 17)
xxvi. *Alternative Wording For Caution Statement* (Laser Notice 30)
xxvii. *User Instruction Hazard Warnings* (Laser Notice 34)
xxviii. *Identification Labels for Certain Class I Laser Products* (Laser Notice 48)
xxix. *Approval of Alternative Means of Labeling for Laser Products* (Laser Notice 53)
xxx. *Guidance on Medical Device Patient Labeling*
xxxi. *Human Factors Principles for Medical Device Labeling*
xxxii. *Labeling – Regulatory Requirements for Medical Devices (FDA 89-4203)*
xxxiii. *Policy on Warning Label Required on Sunlamp Products*
xxxiv. *Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests – Draft Guidance for Industry and FDA Staff*
xxxv. *Guidance for Labeling for Over-the-Counter Sample Collection Systems for Drugs and Abuse Testing*
xxxvi. *Guidance on Labeling for Laboratory Tests – Draft Guidance for Industry and for FDA Reviewers/Staff*
xxxvii. *Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions*

B. Advertising and Promotional Materials:

i. *Accelerated Approval Products: Submission of Promotional Materials* (Draft)
ii. *Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling* (Final)
iii. *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* (Draft)
iv. *Consumer-Directed Broadcast Advertisements* (Final)
v. *Consumer-Directed Broadcast Advertising of Restricted Devices* (Draft)
vi. *"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (Draft)*
vii. *Industry-Supported Scientific and Educational Activities* (Final)
viii. *Presenting Risk Information in Prescription Drug and Medical Device Promotion* (Draft)
ix. *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling* (Draft)

C. Risk Management (Drug Safety):

i. *Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review* (Final)
ii. *Drug-Induced Liver Injury: Premarketing Clinical Evaluation* (Final)
iii. *Drug Safety Information – FDA's Communication to the Public* (Final)
iv. *Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications* (Draft)
v. *Post marketing Studies and Clinical Trials – Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act* (Draft)
vi. *Medical Device Use – Safety: Incorporating Human Factors Engineering into Risk Management*
vii. *Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material*

III. Hot Off the Press: Recent FDA Guidance Documents

Below is a list of recent FDA guidances. This list contains guidance documents issued by the Agency in the last three months. The most recent promulgations are listed first.

i. *E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers* (Draft)
ii. *Dosage Delivery Devices for OTC Liquid Drug Products* (Draft)
iii. *SPL Standard for Content of Labeling Technical Qs & As* (Draft)
iv. *Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects* (Final)
v. *Labeling for Human Prescription Drug and Biological Products – Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information* (Final)
vi. *Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment* (Draft)
vii. *Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications* (Draft)
viii. *End-of-Phase 2A Meetings* (Final)
ix. *Microbiological Data for Systemic Antibacterial Drug Products – Development, Analysis, and Presentation* (Draft)
x. *Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers* (Final)
    1. *Annex 9: Tablet Friability General Chapter* (Draft)
    2. *Annex 10: Polyacrylamide Gel Electrophoresis General Chapter*
xi. *Pharmaceutical Components at Risk for Melamine Contamination* (Final)
xii. *E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions* (Draft)
xiii. *Drug-Induced Liver Injury: Premarketing Clinical Evaluation* (Final)
xiv. *Post-marketing Studies and Clinical Trials – Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act*
xv. *ANDAs: Impurities in Drug Substances* (Final)
xvi. *Post-marketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application* (Final)
xvii. *Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting* (Draft)
xviii. *Questions and Answers on Current Good Manufacturing Practices (cGMP) for Drugs (Level 2 Guidance on Penicillin Drugs added)* (Final)
xix. *Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices* (Final)
xx. *Q8(R1) Pharmaceutical Development Revision 1* (Final)
xxi. *Medication Guides – Adding a Toll-free Number for Reporting Adverse Events* (Final)
xxii. *The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application* (Draft)
xxiii. *Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products* (Draft)
xxiv. *Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing* (Final)
xxv. *Presenting Risk Information in Prescription Drug and Medical Device Promotion* (Draft)
xxvi. *Formal Meetings Between the FDA and Sponsors or Applicants* (Final)
xxvii. *Labeling OTC Human Drug Products; Small Entity Compliance Guide* (Final)

[1] Because of the voluminous number of FDA guidances concerning drugs and medical devices, we have included a sampling of guidances concerning labeling, advertising, promotional materials, and risk management. For a complete list of all FDA guidance documents, please visit *www.fda.gov*.

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