Guidance Agenda
New & Revised Draft Guidances
CDER Plans to Publish During
Calendar Year 2020

(See the Good Guidance Practices (GGPs) regulation on this Web page or 21 CFR 10.115 for details about the Guidance Agenda.)

CATEGORY – Biostatistics

- Adjustment for Covariates in Randomized Clinical Trials for Drugs and Biologics Using Nonlinear Models
- Multiple Endpoints in Clinical Trials
- Statistical Aspects of the Design, Analysis and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals

CATEGORY - Clinical/Antimicrobial

- Development of Anti-Infective Drugs for the Pediatric Population

CATEGORY - Clinical/Medical

- Contact Dermatitis from Topical Drug Products for Cutaneous Application: Human Safety Assessment
- Cross Labeling Oncology Drugs in Combination Drug Regimens
- Decentralized Clinical Trials
- Development of Non-Opioid Analgesics for Acute Pain
- Drug and Biological Products for Major Depressive Disorder: Tables and Figures in the Clinical Studies Section of Labeling-Content and Format
- Initiating Clinical Investigation in Children with Inborn Errors of Metabolism: Ethical Considerations
- Pregnancy Prevention and Planning – Recommendations for Pregnancy Testing and Contraception for Drugs with Teratogenic Potential
- Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control
- Use of Data Monitoring Committees in Controlled Clinical Trials
- Use of Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

CATEGORY - Clinical Pharmacology

- Assessing the Effects of Food on Drugs in INDs or NDAs – General Considerations
- Clinical Drug Interaction Studies with Combined Oral Contraceptives
- Dose Selection in Drug Development
- Drug-Drug Interaction Assessment for Therapeutic Proteins
- Drug Interaction Section of Labeling for Human Prescription Drug and Biological Products- Content and Format
- Evaluation of Gastric pH Mediated Drug Interactions with Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications
- Exposure Response Relationships; Guidance for Industry
- General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products
- Pharmacogenomic Data Submission
- Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis and Impact on Dosing and Labeling; Revised Draft
- Regulatory Considerations for Diagnostic Devices that Reference Therapeutic Products

CATEGORY - Drug Safety

- Best Practices in Developing Proprietary Names for Human Non-Prescription Drug Products
- Definitions of Suspect Product Revised Guidance under the Drug Supply Chain Security Act
- Investigator Responsibilities − Safety Reporting for Investigational Drugs and Devices
- Post-marketing Safety Reporting for Human Drugs and Biological Products Including Vaccines, Revised Draft
- Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act
- Submitting Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989
- Restricted Delivery Systems: Flow Restrictors and Oral Liquid Drug Products
- Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies

CATEGORY - Electronic Submissions

- Establishment Registration and Drug Listing
- Providing Regulatory Submissions in Alternate Electronic Format
- Providing Regulatory Submissions in Electronic Format – Bioanalytical Methods Data Standards

CATEGORY - Generics

- 180-Day Exclusivity: Questions and Answers; Revised Draft
- ANDA Submissions – Refuse-to-Receive for DMF Facilities Deficiencies
- ANDA Submissions – Refuse-to-Receive Standards: Questions and Answers

- Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs; Revised Draft
- Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for Abbreviated New Drug Applications; Revised Draft
- Bioequivalence Studies with Pharmacokinetic Endpoints for Drug Products Submitted under an ANDA; Revised Draft
- Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA; Revised Draft
- Evaluation of Therapeutic Equivalence
- Failure to Timely Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe
- Handling and Retention of BA and BE Testing Samples
- Impact of Court Orders on 30 month Stay of Approval
- In Vitro Permeation Tests for Semisolid Topical Products Submitted in ANDAs
- In Vitro Release Tests for Semisolid Topical Products Submitted in ANDAs
- Orange Book – Questions and Answers
- Pediatric Exclusivity General Considerations for ANDAs
- Physico-Structural (Q3) Characterization of Topical Dermatological Drug Products Submitted in ANDAs
- Revising ANDA Labeling Following Revision of the RLD Labeling
- Sameness Evaluations in an ANDA – Active Ingredients
- Statistical Approaches to Establishing Bioequivalence
- Three-Year Exclusivity Determinations for Drug Products

CATEGORY - Labeling

- Dose Banding: Considerations for Labeling
- Geriatric Information in Human Prescription Drug and Biological Product Labeling; Revised Guidance
- Pregnancy, Lactation and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products; Revised Draft
- Quantification of Sodium, Potassium, and Phosphate in Human Over-the-Counter and Prescription Drug Labeling
- Regulatory Considerations for Prescription Drug-Use-Related Software Output

CATEGORY – Marketing/Advertising

- Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products--Questions and Answers

CATEGORY- Over-the-Counter Drugs

- Annual Reportable Labeling Changes— New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) for a Nonprescription Drug Product

CATEGORY – Pharmaceutical Quality CGMP

- PET Drugs - Current Good Manufacturing Practice (CGMP); Revised Draft

CATEGORY – Pharmaceutical Quality/CMC

- ANDAs: Stability Testing of Drug Substances and Products Questions and Answers
- Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research
- Chemistry Manufacturing and Controls Considerations for Individualize Antisense Oligonucleotide (ASO) Therapies
- Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations
- ICH Q12, General Considerations for FDA Implementation
- Inspection of Injectable Products for Visible Particulates
- Quality Considerations for Topical Ophthalmic Drug Products
- Quality and Stability Testing of Drug Substances and Drug Products for NDAs, ANDAs, and BLAs and Associated Labeling Statements for Drug Products
- Risk Management Plans to Mitigate the Potential for Drug Shortages
- Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biologics
- The Use of Physiologically Based Pharmacokinetic Analyses — Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls

CATEGORY – Pharmaceutical Quality/Microbiology

- Microbiological Quality Considerations in Non-Sterile Drug Product Manufacturing
- Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biologics

CATEGORY – Procedural

- Civil Monetary Penalties for Failure to Meet Accelerated Post Marketing Requirements
- Designated Delivery Services for 505(b)(2) or ANDA Applicants Sending Notices of Paragraph IV Patent Certification
- Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (Revision 1)
- IND submissions for Individualized Antisense Oligonucleotide Therapies: Administrative and Procedural Recommendations Guidance for Sponsor-Investigators
- Identifying Trading Partners under the Drug Supply Chain Security Act; Revised Guidance
- Key Information and Facilitating Understanding in Informed Consent for FDA-Regulated Clinical Investigations
- Notifying FDA of Permanent Discontinuance or Interruption in Manufacturing or Drug or Biological Product
- Pediatric Product Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Scientific Considerations; Revised Draft

- Pediatric Product Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Regulatory Considerations; Revised Draft
- Risk Management Plans to Mitigate the Potential for Drug Shortages
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Revised Guidance
- Tropical Disease Priority Review Vouchers

Note: Agenda items reflect draft and revised draft guidances under development as of the date of this posting.