

# **CDER Guidance Agenda**

## **New, Revised Draft and Immediately in Effect Guidances Planned for Publication in Calendar Year 2024<sup>1</sup> (July 2024)**

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

### **CATEGORY – Administrative/Procedural**

- Accelerated Approval of Drugs and Biologics
- Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers<sup>2</sup>
- Civil Monetary Penalties for Failure to Meet Accelerated Post Marketing Requirements
- Exclusivity for First Interchangeable Biosimilar Biological Products
- Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products
- Key Information and Facilitating Understanding in Informed Consent<sup>3</sup>
- NDC Creation, Assignment, Listing and Appropriate Use for Human Drugs, Including Biological Products
- Priority Review Voucher Programs
- Qualified Infectious Disease Product Designation—Questions and Answers
- Repackaging and Relabeling of Human Drugs: Labeling; Registration and Listing, Safety Reporting, Supply Chain Security, and Good Manufacturing Practice
- Responding to Form FDA 483 Observations at the Conclusion of a Drug CGMP

### **CATEGORY – Biosimilars**

- Considerations in Demonstrating Interchangeability with a Reference Product: Update<sup>3</sup>
- Pediatric Study Plans for Biosimilar Products
- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (Revision 1)<sup>2</sup>
- Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations<sup>2</sup>

### **CATEGORY – Clinical/Antimicrobial**

- Malaria: Developing Drugs for Treatment<sup>2</sup>

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<sup>1</sup> CDER is not bound by this list of topics nor required to issue every guidance document on this list. We are not precluded from developing guidance documents on topics not on this list.

<sup>2</sup> Added since the January 2024 posting.

<sup>3</sup> Published since the January 2024 posting.

## **CATEGORY – Clinical/Medical<sup>4</sup>**

- Chronic Spontaneous Urticaria: Developing Drugs for Treatment<sup>5</sup>
- Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products<sup>6</sup>
- Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drugs and Biological Products
- Developing Drugs for Optical Imaging<sup>7</sup>
- Development of Animal-Derived Thyroid Products
- Development of Non-Opioid Analgesics for Chronic Pain
- Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products
- Drugs With Teratogenic Potential-Recommendations for Pregnancy Planning and Prevention
- Early Alzheimer’s Disease: Developing Drugs for Treatment; Revised Draft<sup>6</sup>
- Endometriosis-Associated Pain: Establishing Effectiveness and Safety of Drugs for Management
- Erosive Esophagitis: Developing Drugs for Treatment<sup>5</sup>
- Obesity: Developing Products to Reduce Excess Body Weight and Maintain Weight Reduction Long Term Revised Draft<sup>8</sup>
- Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment<sup>6</sup>
- Postoperative Nausea and Vomiting: Developing Drugs for Prevention<sup>5</sup>
- Protocol Deviations
- Radiation Dosimetry for First-in-Human Studies of Positron Emission Tomography Drugs
- Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations; Revised Draft<sup>5</sup>
- Study of Sex Differences in the Clinical Evaluation of Medical Products
- Symptomatic Nonerosive Gastroesophageal Reflux Disease: Developing Drugs for Treatment<sup>5</sup>
- Use of Data Monitoring Committees in Controlled Clinical Trials<sup>6</sup>

## **CATEGORY – Clinical Pharmacology**

- Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling

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<sup>4</sup> “Chronic Pain: Developing Drugs for Treatment” included on the January 2024 guidance agenda is the same as “Development of Non-Opioid Analgesics for Chronic Pain” so removed from the July guidance agenda.

<sup>5</sup> Added since the January 2024 posting.

<sup>6</sup> Published since the January 2024 posting.

<sup>7</sup> Title updated from “Optical Imaging: Developing Drugs for Surgical Oncology”.

<sup>8</sup> Title updated from “Developing Products for Chronic Weight Management”.

## **CATEGORY – Compounding**

- Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Draft
- Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Revised Draft
- Compounding Under Section 503B of the Federal Food, Drug and Cosmetic Act and Considerations for Related to Drug Shortages<sup>9</sup>
- Nomination of Bulk Drug Substances for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act
- Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Draft
- Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug and Cosmetic Act<sup>9</sup>
- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors-Guidance for Outsourcing Facilities Under Section 503B of the FD&C Act

## **CATEGORY – Drug Development Tools**

- Biomarker Qualification: Evidentiary Framework

## **CATEGORY – Drug Safety**

- Development of a Shared System or Separate REMS; Revised Draft
- Purpose and Content of Use-Related Risk Analyses<sup>10</sup>
- REMS Logic Model: A Framework to Link Program Design with Assessment<sup>10</sup>

## **CATEGORY – Generics**

- 180-Day Exclusivity: Questions and Answers; Revised Draft
- 30-Month Stay of Approval of an ANDA or 505(b)(2) Application
- 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
- Product-Specific Guidances for Generic Drug Development<sup>11</sup>
- Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; Revised Draft

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<sup>9</sup> Added since the January 2024 posting.

<sup>10</sup> Published since the January 2024 posting.

<sup>11</sup> Title updated from “Bioequivalence Recommendations for Specific Products”.

- Content and Format of Composition Tables in NDAs and ANDAs And Corresponding Statement of Ingredients in Labeling<sup>12</sup>
- Data Integrity for In Vivo Bioavailability and Bioequivalence Studies<sup>12</sup>
- Determining Whether to Submit an ANDA or 505(b)(2) Application
- Form FDA 3542a and Form FDA 3542: Questions and Answers
- Handling and Retention of BA and BE Testing Samples<sup>12</sup>
- In Vitro Permeation Tests for Semisolid Topical Products Submitted in ANDAs; Revised Draft
- In Vitro Release Tests for Semisolid Topical Products Submitted in ANDAs; Revised Draft
- Mechanistic Modeling and Simulation Approaches for Non-Orally Administered (locally applied) Drug Products
- New Clinical Investigation Exclusivity for Drug Products: Questions and Answers
- “Open for Business” Definition Under 744B of the Federal Food, Drug and Cosmetic Act
- Submission of Patent Information for Listing in the Orange Book
- Pediatric Exclusivity General Considerations for ANDAs
- Physico-Structural (Q3) Characterization of Topical Dermatological Drug Products Submitted in ANDAs; Revised Draft

## **CATEGORY – ICH**

- E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports<sup>12</sup>
- E6(R3) Good Clinical Practice Annex 2
- E20 Adaptive Clinical Trials
- M4Q(R2) Addressing Common Technical Document (CTD) Quality-Related Questions<sup>13</sup>
- M13B Bioequivalence for Additional Solid, Oral Dosage Strengths Including Biowaiver Considerations
- M14 General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies that Utilize Real World Data for Safety Assessment of Medicines<sup>14</sup>
- M15 MIDD General Principles
- Q1/Q5C Targeted Revisions of ICH Stability Guidelines
- Q3E Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics
- Q5A(R2) Biotechnology Products Derived from Cell Lines of Human or Animal Origin<sup>12</sup>

## **CATEGORY – Labeling**

- Combined Hormonal Contraceptives for Prevention of Pregnancy-Labeling for Health Care Providers and Patients

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<sup>12</sup> Published since the January 2024 posting.

<sup>13</sup> Title updated from “M4Q(R2) Revision of M4Q(R1) CTD on Quality”.

<sup>14</sup> Title updated from “General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment” and published since the January 2024 posting.

- Drug Interaction Section of Labeling for Human Prescription Drug and Biological Products – Content and Format
- Impact of Identifying Group Purchasing Organizations on a Drug Label

### **CATEGORY – Over-the-Counter Drugs**

- Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products<sup>15</sup>
- Formal Dispute Resolution and Consolidated Proceedings: Requestor of OMUFA Products Appeals Above the Division Level

### **CATEGORY – Pharmaceutical Quality CGMP**

- PET Drugs - Current Good Manufacturing Practice (CGMP); Revised Draft
- Laboratory Testing of Drugs Held in Interstate Commerce: Compliance with CGMP
- Approaches to Meeting CGMP Requirements for Distributed Manufacturing

### **CATEGORY – Pharmaceutical Quality/CMC**

- ANDAs: Stability Testing of Drug Substances and Products Q & A
- Container Closure Systems for Drugs, Including Biological Products
- Considerations for Complying with 21 CFR 211.110
- Control of Nitrosamine Impurities in Human Drugs; Immediately in Effect Upon Publication (Revision 2)
- Stability Considerations for Drug Substances and Drug Products in NDAs, ANDAs, and BLAs and Associated Labeling Statements for Drug Products
- Stability Recommendations for Additional Manufacturing Facilities in NDAs, ANDAs and BLAs, and Additional Drug Substance Sources in NDAs and ANDAs
- Postapproval Manufacturing Changes to Biosimilars and Interchangeable Biosimilars: Questions and Answers
- Quality Management Maturity Program Draft Guidance
- Platform Technology Designation Program for Drug Development<sup>15</sup>
- Container Closure System and Component Changes: Glass Vials and Stoppers; Immediately in Effect

### **CATEGORY – Pharmacology/Toxicology<sup>16</sup>**

- Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics
- Recommended Follow-Up Testing for an Ames-Positive Drug or Metabolite To Support First-in-Human Clinical Trials With Healthy Subjects

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<sup>15</sup> Published since the January 2024 posting.

<sup>16</sup> Added since the January 2024 posting.

## **CATEGORY – Promotional Labeling and Advertising**

- Promotional Labeling and Advertising Considerations for Prescription Biological Reference, Biosimilar, and Interchangeable Products – Questions and Answers<sup>17</sup>

## **CATEGORY – Real-World Data/Real-World Evidence (RWD/RWE)**

- Considerations Regarding Non-Interventional Studies for Drug and Biological Products<sup>17</sup>
- Using Clinical Practice Data in Randomized Controlled Trials (RCT) for Regulatory Decision-Making for Drug and Biological Products
- Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice

*Note: Agenda items reflect guidances under development as of the date of this posting.*

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<sup>17</sup> Published since January 2024 posting.