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RE: FDA Guidance, Compliance and Regulatory Information

1 Access Links to the FDA Biosimilars and Other Information

1.1 The Following List Provides a List of Important Links to the FDA Biosimilar Guidances

Category	Title	Type	Date
Procedural; Biosimilarity	Reference Product Exclusivity for Biological Products Filed Under (PDF - 99KB)	Draft Guidance	08/04/14
Biosimilarity	Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (PDF - 142KB)	Draft Guidance	05/13/14
Biosimilarity; Procedural	Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants (PDF - 272KB)	Draft Guidance	03/29/13
Biosimilarity	Guidance for Industry on Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009	Draft Guidance Updated for 508 compliance.	02/09/12
Biosimilarity	Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (PDF - 576KB)	Draft Guidance	02/09/12
Biosimilarity	Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product (PDF - 432KB)	Draft Guidance	02/09/12

1.2 Other FDA Guidance, Compliance and Regulatory Information

- Guidances (Drugs)
- Advertising
- Animal Rule
- Biopharmaceutics
- Clinical / Antimicrobial
- Clinical / Medical
- Clinical Pharmacology
- Combination Products
- Concept Papers
- Current Good Manufacturing Practices (CGMPs)/Compliance
- Drug Development Tools
- Drug Safety

- Electronic Submissions
- FDAAA (Food and Drug Administration Amendments Act)
- **Generics**
- Good Review Practices
- Industry Letters
- Industry Letters
- International Conference on Harmonisation - Efficacy
- International Conference on Harmonisation - Joint Safety/Efficacy (Multidisciplinary)
- International Conference on Harmonisation - Quality
- International Conference on Harmonisation - Safety
- Investigational New Drug Applications
- Labeling
- Modernization Act
- Over-the-Counter
- Pharmaceutical Quality/CMC
- Pharmaceutical Quality/Microbiology
- Pharmacology / Toxicology
- Procedural
- Product-Specific Recommendations for Generic Drug Development
- Rare Diseases
- Small Entity Compliance Guides
- User Fees

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