

Handbook of biogeneric therapeutic proteins - regulatory, manufacturing, testing, and patent issues

Taylor & Francis - FDA Reform: Promote the Approval of Life

Candidate	Original Name (Sponsor)	Comparability	Pre-Clinical	Clinical	Approved
B00115	Infliximab (Amgen)				2015
B00115	Infliximab (Amgen)	Comparability: CTA			2017
B00115	Infliximab (Amgen)	Comparability: CTA			2018
B00115	Infliximab (Amgen)	Comparability: CTA			2019
B00115	Infliximab (Amgen)	Comparability: CTA			2020
B00115	Infliximab (Amgen)	Comparability: CTA			2021
B00115	Infliximab (Amgen)	Comparability: CTA			2022
B00115	Infliximab (Amgen)	Comparability: CTA			2023

Description: -

Technology, Pharmaceutical.

Drug Industry.

Recombinant Proteins -- therapeutic use.

Pharmaceutical biotechnology industry.

Recombinant proteins.

Generic drugs.

Protein drugs. Handbook of biogeneric therapeutic proteins -

regulatory, manufacturing, testing, and patent issues

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Notes: Includes bibliographical references and index.

This edition was published in 2006



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Tags: #Handbook #of #Pharmaceutical #Manufacturing #Formulations, #Third #Edition

Regulatory and Development Issues in the Demonstration of Therapeutic Equivalence for Multisource Biotech

Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin. Throughout the growth process the cells are fed and maintained in an environment of monitored and dynamically changed temperature, pH, and other characteristics such as dissolved oxygen and carbon dioxide.

Handbook of Biogeneric Therapeutic Proteins

The absence of an Orange-Book-style registry of patents covering licensed biologics makes this endeavor more complicated than a hypothetical analogous pharmaceutical regime. The validation and standardization of assays will be crucial for future testing and regulation of biosimilars.

C.H.I.P.S. Alphabetical Title List Handbook of A

At least one challenge with the approach of using clinical trials as the final arbiter of similarity parallels the growing recognition that clinical trials are generally too small and too short to evaluate negative effects of drugs that may only arise in the longer term or in limited populations.

Quality by Design applications in biosimilar pharmaceutical products

Physician awareness of potential differences between biopharmaceuticals and biosimilars and the impact on safety and efficacy is critical for patient safety. The Enbrel patent disclosure thus exemplifies both problems noted above.

C.H.I.P.S. Alphabetical Title List Handbook of A

FDA Action Date The action date tells when an FDA regulatory action, such as an original or supplemental approval, took place.

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition

It then discusses three cases exemplifying different strategies on the part of firms and government actors.

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Schondelmeyer, PhD, and two anonymous reviewers for their valuable feedback and assistance. If, however, biosimilars differ in ways that would only be noticed in post-market surveillance—as seems likely, based on the path-dependence differences described above, see *supra* Part II.

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