CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF SIMILAR BIOTHERAPEUTIC PRODUCTS

A. Initial Application

Part I: Administrative Data and Product Information
Sec. A Introduction
Sec. B Overall Table of Contents
Sec. C Guidance on the Administrative Data and Product Information

1. Application Form
2. Letter of Authorization (where applicable)
3. Certifications

For contract manufacturing
- a. License of pharmaceutical industries and contract manufacturer
- b. Contract manufacturing agreement
- c. GMP certificate of contract manufacturer

For manufacturing "under-license"
- a. License of pharmaceutical industries
- b. GMP certificate of the manufacturer
- c. Copy of "under-license" agreement

For locally manufactured
- a. License of pharmaceutical industries
- b. GMP certificate (country specific)

For imported products
- a. License of pharmaceutical industries/importer/wholesaler (country specific)
- b. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format

4. Labeling
5. Product Information
   - 5.1. Package Insert
   - 5.2. Summary of Product Characteristics (Product Data Sheet)

Part II: Quality
Sec. A Table of Contents
Sec. B Quality Overall Summary
Sec. C Body of Data

Drug Substance (S)

S 1 General Information
- S 1.1. Nomenclature
- S 1.2. Structural Formula
- S 1.3. General Properties

S 2 Manufacture
- S 2.1. Manufacturer(s)

- S 2.2. Description of Manufacturing Process and Process Controls
- S 2.3. Control of Materials
- S 2.4. Control of Critical Steps and Intermediates
- S 2.5. Process Validation and/or Evaluation
- S 2.6. Manufacturing Process Development

S 3 Characterization
- S 3.1. Elucidation of Structure and Characteristics
- S 3.2. Impurities

S 4 Control of Drug Substance
- S 4.1. Specifications
- S 4.2. Analytical Procedures
- S 4.3. Validation of Analytical Procedures
- S 4.4. Batch Analyses
- S 4.5. Justification of Specifications

S 5 Reference Standards or Materials

S 6 Container Closure System

S 7 Stability

Drug Product (P)

P 1 Description and Composition

P 2 Pharmaceutical Development
- P 2.1. Information on Development Studies
- P 2.2. Components of the Drug Product
  - P 2.2.1. Active Ingredients
  - P 2.2.2. Excipients
- P 2.3. Finished Product
  - P 2.3.1. Formulation Development
  - P 2.3.2. Overages
  - P 2.3.3. Physicochemical and Biological Properties
- P 2.4. Manufacturing Process Development
- P 2.5. Container Closure System
- P 2.6. Microbiological Attributes
- P 2.7. Compatibility

P 3 Manufacture
- P 3.1. Batch Formula
- P 3.2. Manufacturing Process and Process Control
- P 3.3. Controls of Critical Steps and Intermediates
- P 3.4. Process Validation and/or Evaluation

P 4 Control of Excipients
- P 4.1. Specifications
- P 4.2. Analytical Procedures
- P 4.3. Excipients of Human and Animal Origin
- P 4.4. Novel Excipients

P 5 Control of Finished Product
- P 5.1. Specifications
- P 5.2. Analytical Procedures
- P 5.3. Validation of Analytical Procedures
- P 5.4. Batch Analyses
- P 5.5. Characterization of Impurities
- P 5.6. Justification of Specifications

P 6 Reference Standards or Materials
P 7 Container Closure System
P 8 Product Stability
P 9 Quality Comparability
- P 9.1. Reference Biotherapeutic Product
- P 9.2. Manufacturing Process
- P 9.3. Characterization
  - P 9.3.1. Physicochemical Properties
  - P 9.3.2. Biological Activity
  - P 9.3.3. Immunochemical Properties
  - P 9.3.4. Impurities
- P 9.4. Specifications
- P 9.5. Analytical Techniques
- P 9.6. Stability

Part III: Nonclinical Document
Sec. A Table of Contents
Sec. B Nonclinical Overview
1. General Consideration
2. Special Consideration
   - 2.1. In Vitro Studies
   - 2.2. In Vivo Studies

Part IV: Clinical Document
Sec. A Table of Contents
Sec. B Clinical Overview
1. Pharmacokinetic Studies
2. Pharmacodynamic Studies
3. Confirmatory Pharmacokinetic/Pharmacodynamic Studies
4. Efficacy Studies
5. Safety Studies
6. Immunogenicity
7. Extrapolation of Efficacy and Safety Data

Additional Requirements:

1) Representative Sample with corresponding Certificate of Analysis
2) Risk Management Plan
3) For imported products:
   (a) Foreign GMP Clearance

B. Renewal Application

1) Integrated Application Form
2) Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP)
3) Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated
4) Labeling Materials (actual/commercial)
5) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)
2) For products qualifying for Generic Labeling Exemption (GLE):
   (a) Request for GLE

Notes:

- All documentary requirements must be in PDF format to be submitted to PAIR
- Image files should be at least 150 dots per inch (dpi)
- A hard copy of the integrated application form is required
- Samples may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System
- ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions