Appendix 6

Documents for the Application for Drug Review and Registration of Bio-Pharmaceutical Products

Documents should be submitted (NOTE5)	Genetic engineering drugs (including bio-similars) (NOTE3)	Vaccines	Drugs derived from human blood	Allergen drugs	Others
Application fees	○	○	○	○	○
Application form (original copy and duplicate copy)	○	○	○	○	○
Assurance statement (A)	○	○	○	○	○
Assurance statement (B)	○	○	○	○	○
Form for sticking label and package insert (two copies)	○	○	○	○	○
Form for sticking license	○	○	○	○	○
Batch records of tentative manufacturing	○	○	○	○	○
Testing specifications, methods and results of active pharmaceutical ingredients (two copies)	○	○	○	○	○
Testing specifications, methods and results of excipient (two copies)	○	○	○	○	○
Testing specifications, methods and results of final products (two copies)	○	○	○	○	○
Written operational procedures of stability study and reports	○	○	○	○	○
CPP (Note1)	△	△	△	△	△
CPP of source country (imported products), formulation basis (local products)	○	○	○	○	○
Authorization letter (imported products)	○	○	○	○	○
Photocopy of GMP compliance certificate	○	○	○	○	○
Validation documents of analytical methods (two copies)	○	○	○	○	○
Validation documents of critical manufacturing process (two copies) (Note2)	○	○	○	○	○

Source certificate and the SOP for the control of the sources of animal raw materials used in the manufacturing processes, or a certificate issued by the original manufacturer to justify that no animal raw materials are used in the manufacturing processes.	○	○	○	○	○
Drug testing (Note4)	△	○	○	╳	△
Technical data	Follow the regulations set out in Appendix 7				

Note:

○: submission is a must; △: submission is on a case-by-case basis; ╳: submission is not necessary

1 CPP related regulations are as follows,

Four categories of bio-pharmaceutical products (including bio-similars): genetic engineering drugs, vaccines, products derived from human blood, allergen drugs:

(1) If a similar product (identical in sources and ingredients) has already been launched in Taiwan, then the CPP can be replaced by the source country's FSC.

(2) If no similar product (identical in sources and ingredients) has been launched in Taiwan, then the submission should comply with regulations set out in Article 38、38-1、38-2、38-3、38-4 and 38-5.

2 If the application product is an imported sterile preparation, then the documents of critical manufacturing processes should include sterilization validation.

3 Bio-similar products refer to bio-products derived from bio-technology and with similar quality, safety and effectiveness to reference bio-pharmaceutical products that have been licensed in Taiwan.

4 Allergen drugs: According to Article 24 Paragraph 2, the assessment can be done through dossier review instead of sample testing, except for those cases deemed by the central health competent authority that drug testing is necessary.

5 Application dossiers shall be submitted according to the Common Technical Document (CTD) format.