MOHW FDA No. 1091105341 Announcement dated August 31, 2020 "

Notices for the application of Plant master file **Form C-1 revised version**

Plant Master File (PMF) Checklist for Foreign Pharmaceutical Manufacturer

Form C-1: Documents in Common review (For the expansion of manufacturing site, the items which are marked with asterisk are required, and the relevant documents shall be enclosed.)

Applicant:	**Receipt No.**	**Case Number**
Item	Please complete the Checklist item by item and indicate the attachment numbers or the page numbers of **submitted documents**	reviewer comment
*1.1 Name of manufacturer (which shall be consistent with that shown in the official supporting documents)	P.	
*1.2 Address of manufacturer (which shall be exact detailed and consistent with that shown in the official supporting documents; and give both contact address and site address, if different)	P.	
1.3 Legalization requirements: Based on Article 5, Paragraph 2 of the "Regulations of Medicament Manufacturer Inspection, the PMF application materials may meet any one of the following requirements for submission:: ☐ PMF or SMF, which is to be certified by the highest competent health authority or the chamber of commerce in the country of origin or legalized by the embassy, representative office or agencies authorized by the Ministry of Foreign Affairs of R.O.C. ☐ Original copy or original certified photocopy of the Certificate of Compliance with the local Good Manufacturing Practice issued by the highest competent health authority in the original country or legalized by the embassy, representative office or agencies authorized by the Ministry of Foreign Affairs of R.O.C. (if the two original documents mentioned above were already submitted to the TFDA through other cases, a photocopy of the whole document may be enclosed, with indication of the case number	P.	

where the original copies were submitted to the TFDA) ☐Original copy or original certified photocopy of the Certificate of Pharmaceutical Product manufactured in compliance with the local Good Manufacturing Practice issued by the highest competent health authority in the original country or legalized by the embassy, representative office or agencies authorized by the Ministry of Foreign Affairs of R.O.C. (if the two original documents mentioned above were already submitted to the TFDA through other cases, a photocopy of the whole document may be enclosed, with indication of the case number where the original copies were submitted to the TFDA) ☐If the paper based GMP certification is no longer issued in the original country, or the drug product is contracted manufacturing, the license holder of the imported drug shall state why the GMP certification is not submitted. Therefore, the applicants may submit the original copy or photocopy with legalization of the Certificate of Pharmaceutical Product issued by any one of A 10 countries or the CPP issued by the EMA (European Medicine's Agency), or by the highest competent health authority in the country where the contractor is located, in accordance with the letter TFDA Risk No. 1051105400 dated October 17, 2016.		
*1.4 Dosage form /product/ operations involved in the current application *1.4.1 To be completed independently by the Taiwan agent, with indication of the manufacturing process stage being applied for. For biological medicinal products, and blood products derives from human blood or plasma, the product / dosage form and manufacturing process stage shall be specified, and the following items shall be checked: ☐ Animal sourced products ☐ Allergen products ☐ Animal immunosera products ☐ Vaccines ☐Recombinant products ☐ Monoclonal antibody products ☐Transgenic animal products ☐ Transgenic plant products ☐ Gene therapy products ☐ Somatic and xenogenic cell therapy products and tissue engineered products	P.	

☐ Blood products		
*1.4.2 Explain whether the manufacturing and testing is **full-manufacturing process** or **phased**. **If the production or testing is phased, the implementation stage in the manufacturing site shall be specified separately.** **For applicants applying simplified review for non sterile dosage form except secondary packaging, the flowchart of major manufacturing steps for the applied dosage form/manufacturing process are required.**	P.	
*1.4.3 Enclose the layout of production area ~~layout~~ (from weighing to secondary packaging)	P.	
*1.4.4 Explain if special products (biological medicinal products, highly sensitizing, highly pharmacological active, toxic, or hazardous substances) are included, such as β-lactam antibiotics (e.g., penicillin, cephalosporins, Penem, Carbacephems, Monobactams), Hormone(include sex hormones and non-sex hormones), cytotoxics, or radioactive medicinal products.	P.	
1.5 The approval letter holds by applicant or other agent. ☐The TFDA issued approval letter holds by applicant already, enclose photocopies ☐The TFDA-issued approval letter holds by other agent, enclose photocopies. (Describe the dosage form and the manufacturing process)	P.	
1.6 Overview of the manufacturing site		
1.6.1 Briefly describe the premises (area, location, surroundings)	P.	
1.6.2 Site layout, with indication of purposes of respective buildings in the site	P.	
1.6.3 Describe whether the outsourced activities and the contract meet the regulations in PIC/S GMP, Chapter 7.	P.	
1.7 Manufacturing items at the site approved by the competent authority in the original country (**photocopy of the official document**)	P.	
*1.8 Description of the all production in the site		

*1.8.1 List the products actually manufactured in the manufacturing site by their dosage forms and their active ingredient (including contract manufacturing given and accepted), and enclose a list. If original materials provided by the manufacturer are not listed by dosage forms, the Taiwan agent is asked to sort and list them by-the dosage forms.	P.	
*1.8.2 Are specific products manufactured in the site? (If yes, go on to complete 1.8.2.1—1.8.2.3.)	Y/N	
*1.8.2.1 Clarify the production status of biological medicinal products, highly sensitizing, highly pharmacologic active, toxic, or hazardous substances (including the type of active ingredient and the dosage form), such as β-lactam antibiotics (e.g., penicillins, cephalosporins, Penem, Carbacephems, Monobactams), Hormone(include sex hormones and non-sex hormones), cytotoxics, and radioactive medicinal products.	P.	
*1.8.2.2 If specific products indicated in 1.8.2.1 are manufactured, please specify the production status of the products, such as how the manufacturing premises, facilities, and equipment are laid out (separate premises, separate production areas, dedicated equipment in the shared production areas or shared facilities and equipment with non-specific medicinal products, etc.) and **indicate production areas for said products in the layout.**	P.	
*1.8.2.3 For dedicated equipment in the shared production areas or shared facilities and equipment with non-specific medicinal products, measures to prevent cross-contamination and their effectiveness reviewed periodically shall be submitted.	P.	
*1.8.3 Are other non-human medicinal products (such as veterinary medicinal products), diagnostic reagents, medical devices, cosmetics, foods, herbal medicine or other products (such as investigational medicinal products) also manufactured in the site? (If yes, go on to complete 1.8.3.1—1.8.3.2.2.)	Y/N	
*1.8.3.1 If the certain products indicated in 1.8.3 are produced, please specify the **type of**	P.	

product, the composition, and whether the ingredients are usable in the human body, and enclose supporting materials.		
*1.8.3.2 If the certain products indicated in 1.8.3 are produced, please specify the production status such as how the manufacturing premises, facilities, and equipment are laid out (separate premises, separate production areas, dedicated equipment in the shared production areas or shared facilities and equipment with human medicinal products, etc.), and **indicate production areas for said products in the layout.**	P.	
*1.8.3.2.1 For dedicated equipment in the shared production areas with human medicinal products , the following shall be described: A. Is the active ingredient of certain products archived in the pharmacopoeia? If yes, enclose relevant bases. B. Is the manufacturing in compliance with the PIC/S GMP standards?(The statement is written and signed by the original manufacturer) C. Measures to prevent cross-contamination and their effectiveness shall be reviewed periodically.	P.	
*1.8.3.2.2 For shared facilities and equipment with human medicinal products, the following shall be described in detail: A. Is the active ingredient of certain products archived in the pharmacopoeia? If yes, enclose relevant bases. B. Is the manufacturing in compliance with the PIC/S GMP standards? C. Measures to prevent cross-contamination and their effectiveness shall be reviewed periodically. D. If the veterinary medicinal products and human medicinal products are manufactured at the same facilities and share same equipment, the said veterinary medicinal products are not used in Human, the following dossiers	P.	

	shall be required, the risk assessment report including toxicological data, Health Based Exposure Limit (HBEL)PDE /ADE , and correspondence measurements to prevent from cross contamination .(If the veterinary medicinal products are not manufactured from weighing to primary packaging at the same facility which also produce human medicinal products, this item is not required.) E. If the specific products shared facilities and equipments (from weighing to primary packaging) with human medicinal products are veterinary medicinal products, herbal medicine / homeopathic drugs or common products(anti mosquito products, tooth paste, mouthwash, shampoo, etc.), the following requirements shall be enclosed: the list of shared equipments, the list of dosage form and components for all products, describe the implementation of cleaning validation (e.g. single product approach or grouping approach). Where grouping approach is used, describe the categories in detail, and also list the APIs of each product in each group, and the target ingredient for cleaning validation. (If there is no specific products manufactured at the facility of human medicinal products (from weighing to primary packaging), this item is not required.)		
		Signature (including date of signing)	