TFDA Risk No. 1101107078 Announcement dated September 28, 2021

Notices for the Plant Master File (PMF) Application Form B

Checklist of preparing submission dossiers of Plant Master File for Foreign Pharmaceutical manufacturers

Checklist Item	Y/N/NA	Reviewer's comment
0. Official Letter from the Applicant (Taiwan pharmaceutical company) may be enclosed, depending on the needs of the case.	[ ]	
1. Application Form for Plant Master File (PMF) Review for Foreign Pharmaceutical Manufacturers (Form A)	[ ]	
For each case, only one manufacturer site located at a single address shall be applied for.	[ ]	
The name and address of manufacturer shall be consisted with the GMP certificate issued by hosting competent authority (or information published on the web site of hosting competent authority). Document shall be provided to review.	[ ]	
Review fees paid	[ ]	
2. Plant Master File (PMF) Checklist for Foreign Pharmaceutical manufacturer (Form C), which is completed in accordance with the dosage form, product, and manufacturing process being applied for, and:		
Also enclose the documents asked for in the Checklist (not required if applying for quote review for the same dosage form/ biological medicinal product)	[ ]	
Must be completely filled out and signed with wet signature or electronically by the person completing it (from Taiwan pharmaceutical company or the manufacturer's quality assurance department or relevant department)	[ ]	
For each review item, the page number or appendixes of corresponding documents submitted for review are to be specified in the Checklist	[ ]	
3. **Authorization Letter:**		
(1) -1: The original Letter of Authorization whereby the foreign manufacturer authorizes the Taiwan agents (pharmaceutical company) to submit PMF applications. The authorization letter shall be signed with wet signature or electronically by the responsible person of the foreign manufacturer. (1) -2: When applying for quote review, it is also required to enclose the original copy of Letter of Explanation from the manufacturer, specify (i) The manufacturer agrees that Taiwan pharmaceutical company to proceed pursuant to the previous submission, (ii) Approval number of previous GMP approval letter issued by Taiwan FDA, and (iii) Brief description of changes effected since the last PMF application (Not required if applying for the same dosage form/products/manufacturing process)	[ ] [ ]	
(2) When biological medicinal products/biological active	[ ]	

substance/blood products derived from human blood or human plasma are being applied for, the products/dosage forms and manufacturing process stage involved in the application shall be indicated in the Authorization Letter.		
(3) To apply for quote review, it is required to enclose the Letter of Authorization from the Taiwan pharmaceutical company who holds the previous GMP approval letter. (Bearing the company seal and the responsible person's seal.)/The authorization letter shall signed with wet signature or electronically by responsible person. (Not required for original holders applying for quote review.)	[ ]	
4. **Legalization (**For applicants applying for PMF for Quote review and for expansion of manufacturing site, legalization of the dossier is not required.)	[ ]	
5. **Site Master File** (SMF)		
(1) The SMF shall be provided according to "Pharmaceutical manufacturers on the preparation of a site master file" announced by the Ministry of Health and Welfare in TFDA letter DOH FDA No. 1001100562 dated May 2, 2011.	[ ]	
(2) Electronic file of the **latest** Chinese or English version	[ ]	
(3) Hard copy may be submitted	[ ]	
6. **The previous GMP approval letter.** (For applicants applying for PMF for Quote review and for expansion of manufacturing site.)	[ ]	
7. **Alternative** document for simplified review (three in total) *	[ ]	
8. **Alternative** document to substitute the validation and qualification documents (three in total)*	[ ]	
9. Are dossiers format compliant with "**Notices for the application of Plant master file**"?	[ ]	

*Please refer to Notices for the Plant Master File (PMF) Application.