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

Notices for the application of Plant master file" **Form B** revised version

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

Checklist Item	Y/N/NA	To be checked by the reviewer
0. Official Letter from Taiwan agent (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 manufacturing site located at a single address may be applied for.	[ ]	
Pay review fees	[ ]	
2. Plant Master File (PMF) Checklist for Foreign Pharmaceutical manufacturer (Form C), which is to be completed in accordance with the dosage form, product, and operation being applied for, and:		
Also enclose the files and documents asked for in the Checklist (not required if applying for quote review for the same dosage form / biological medicinal product)	[ ]	
Must be original copy, completely filled out and signed by the person completing it (signature of the Taiwan agent) or the manufacturer's quality assurance staff or relevant parties)	[ ]	
For each review item, the page number or appendixes of corresponding materials and documents submitted for review are to be specified in the form	[ ]	
3. **Authorization Letter:**		
(1) -1: The original copy of the Authorization Letter issued by the manufacturer, stating that the Taiwan agent is authorized by the manufacturer to apply for PMF submission. The authorization letter shall be with responsible person's hand-written signature or electronical documents shall be signed electronically. 1) -2: When the application is for quote review, it is also required to enclose the original copy of the Original copy of the Letter of Explanation from the manufacturer, that shall specify [(i) The manufacturer agrees that Taiwan agent could refer to the previous submission dossiers, (ii) Approval number of previous GMP approval letter issued by Taiwan FDA, and (iii) Brief presentation of changes being effected since the last PMF application(Not required if the application is for the same dosage form/products/operations)]	[ ] [ ]	
(2) When biological medicinal products/Blood products 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 agent who holds the previous GMP approval letter. (Bearing the company seal and the responsible person's seal.)/ The authorization letter shall be with responsible person's hand-written signature or electronical documents shall be signed electronically. (Not required for original holders of previous GMP approval letters.)		
4. Legalization **(**For applicants applying for Quote review, legalization of the dossier is not required.)	[ ]	
5. **Site Master File** (SMF)		
(1) The SMF shall be suggested to provide 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	[ ]	
6. Alternative dossiers for simplified review (two in total)*	[ ]	
7. Alternative dossiers to substitute the validation and qualification documents (three in total)*	[ ]	
8. Is document format compliant with "**Notices for the application of Plant master file**"?	[ ]	

*Please refer to Notices for the application of Plant master file.