Notices for the application of Plant master file Form A

Application Form for Plant Master File (PMF) Review for Foreign Pharmaceutical Manufacturers

Date of Application	MM/DD/YYYY	
Applicant	☐Name: (Business License No. of Distributor Pharmaceutical Company _____) ☐Contact: ☐Telephone and Email:	
Submission Serial No. (Leave it blank)	Plant Master File ☐☐☐☐☐☐☐☐	
Country/Name of Manufacturing Plant/Address	☐Country: ☐Name of Manufacturing Plant: ☐Address:	
Description of Application [1] (For each case, up to 3 dosage forms/products/operations may be applied for) ☐New Plant ☐Expansion[2] ☐Addition of dosage form/product/operations	1. ☐ Orphan Drug	☐Non-sterile medicinal products/Secondary packaging ☐ Sterile medicinal products [□Terminal Sterilization □ Aseptically Prepared: □SVP □LVP] ☐ Biological medicinal products ☐ Biological medicinal substances ☐ Products derived from human plasma ☐ATMPs ☐Vaccines _____ The scope of this application includes: □No Specially Toxic & Hazardous Substances □Penicillins □Cephalosporins □Estrogens □Cytotoxics □Others ( )
	2. ☐ Orphan Drug	☐Non-sterile medicinal products/Secondary packaging ☐ Sterile medicinal products [□Terminal Sterilization □ Aseptically Prepared: □SVP □LVP] ☐ Biological medicinal products ☐Biological medicinal substances ☐Products derived from human plasma ☐ATMPs ☐Vaccines _____ The scope of this application includes: □No Specially Toxic & Hazardous Substances □Penicillins □Cephalosporins □Estrogens □Cytotoxics □Others ( )
	3. ☐ Orphan Drug	☐Non-sterile medicinal products/Secondary packaging ☐ Sterile medicinal products [□Terminal Sterilization □ Aseptically Prepared: □SVP □LVP] ☐ Biological medicinal products ☐Biological medicinal substances ☐Products derived from human plasma ☐ATMPs ☐Vaccines _____ The scope of this application includes: □No Specially Toxic & Hazardous Substances □Penicillins □Cephalosporins □Estrogens □Cytotoxics □Others ( )

<table>
<tr><td>Mode of Application (Full/Simplified/ Quote review)</td><td>
<table>
<tr><td></td><td>□ Non-sterile medicinal products /Secondary packaging</td><td>□ Sterile medicinal products</td><td>□Biological medicinal products/ Biological medicinal substances/ Blood products derived from human blood or human plasma</td></tr>
<tr><td>Full review</td><td>□</td><td>□</td><td>□</td></tr>
<tr><td>Simplified review</td><td>□</td><td>□</td><td>□</td></tr>
<tr><td>Alternative dossiers to substitute the Documents of Validation and Qualification</td><td>□</td><td>□</td><td>□</td></tr>
</table>
<table>
<tr><td>Quote review</td><td><u>Non-holder of previous</u> GMP approval letters applying for <u>same</u> dosage forms and/or products</td><td><u>Holder of previous</u> GMP approval letters applying for <u>additional</u> dosage forms and/or products</td><td><u>Non-holder of previous</u> GMP approval letters applying for <u>different</u> dosage forms and/or products</td></tr>
<tr><td>Previous GMP approval letter</td><td colspan="3">☐Overseas on-site inspection
☐PMF review
☐Follow up inspection</td></tr>
<tr><td>Applicable period</td><td colspan="3">Within the effective period of the previous valid GMP approval letter</td></tr>
<tr><td><u>Approval No.</u> and <u>effective period</u> of the GMP approval letter to be quoted</td><td>[ ] [ ]</td><td>[ ] [ ]</td><td>[ ] [ ]</td></tr>
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</td></tr>
<tr><td>Review fees</td><td>According to the latest versions of the "Standards of Review Fees for the Registration of Western Medicines" and the " Standards of Review Fees for the Registration of orphan drug", fees are charged accordingly. Applicants for orphan drugs are required to provide relevant supporting documents of orphan drugs for each application.</td></tr>
<tr><td colspan="2">Remarks:
1. "Description of Application" must be filled out in accordance with the dosage form/manufacturing activity from the TFDA's "Medicinal Product Dosage Form Classification Principles for Medicinal Product Manufacturing Licenses, and dosage forms and manufacturing activity in GMP Determinations".
2. For cases involving expansion, please specify the expansion location (e.g., building name) and the relevant approved details.</td></tr>
</table>

A list of forms to be required for each submission method of PMF application

Forms that must be required	Submission methods								
	Non-sterile medicinal products (Including secondary packaging process)		Sterile medicinal products		ATMPs/ Biological medicinal products /Biological medicinal substances/ Products derived from human plasma		Quote review		
	Simplified[1] review	Full review	Simplified[1] review	Full review	Simplified[1] review	Full review	**Non-holder of previous** GMP approval letters applying for the **same** dosage forms and/or products	**Holder of previous** GMP approval letters applying for **additional** dosage forms and/or products[3]	**Non-holder of previous** GMP approval letters applying for **different** dosage forms and/or products[3]
A Application Form for Plant Master File (PMF) Review for Foreign Pharmaceutical manufacturers	✓	✓	✓	✓	✓	✓	✓	✓	✓
B **Checklist of Preparing submission dossiers of Plant Master File for Foreign Pharmaceutical manufacturers**	✓	✓	✓	✓	✓	✓	✓	✓	✓

C-1 Documents in Common review	✓	✓	✓	✓	✓	✓		✓	✓
C-2 Simplified review: **Sterile medicinal products/ Biological medicinal products/ Biological medicinal substances (including the substance claimed non sterile or low bioburden level) / Blood products derived from human blood or human plasma**			✓		✓			4	4
C-3 Full review: **All products**		✓		✓		✓		4	4
C-4 **Biological medicinal substances and medicinal products /Blood products derived from human blood or human plasma**					✓	✓		4	4
C-5 Validation and Qualification		✓2	✓2	✓2	✓2	✓ 2		4	4

[Remarks and explanation]:

1. To apply for simplified review, the following documents must be enclosed.
   (1) The list of GMP inspections conducted in the last five years (by local and foreign competent health authorities), which shall include at a minimum the date of inspection, topic of inspection, and scope of inspection, among other information.
   (2) Inspection report for the most recent on-site GMP inspection conducted by the local competent health authority (the scope of the inspection shall covered the dosage form and scope of operations applied for as indicated in the PMF) and the GMP certificate (or other GMP approval dossiers which are issued by the local competent health authority). The inspection report shall be the Chinese or an English fully translation, as well as the inspection report in the original text, and the list of major changes to the dosage forms/operation being applied for between said inspection and the date of the current submission (including premises, facilities, equipment, and manufacturing process).
2. For applicants to apply PMF with alternative dossiers to substitute the Documents of Validation and Qualification documents, it is allowed to enclose all three of the following documents instead:

(1) the original copy or hard copy of the Certificate of pharmaceutical products (CPP) issued by any one of the A 10 countries, or the CPP issued by the EMA (European Medicine's Agency)
(2) Validation and qualification summary
(3) Original letter of explanation

3. If the dosage forms and/or manufacturing activity involved in the application is more complex than previous approval letter, the TFDA has the right to request supplementation of relevant documents.
4. Enclose corresponding materials, as required by the dosage form/manufacturing processes involved in the application.
5. 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.
6. For applicants applying PMF for Quote review and for expansion of manufacturing site, legalization of the dossier is not required.