MOHW FDA No. 1091105341 Announcement dated August 31, 2020 "**Notices for the application of Plant master file**" Form A revised version

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

<table>
<tr><td>Date of Application</td><td>MM/DD/YYYY</td></tr>
<tr><td>Applicant</td><td>☐Name:
(Business License No. of Distributor Pharmaceutical Company _____)
☐Contact:
☐Telephone/Email:</td></tr>
<tr><td>*Submission Serial No.</td><td>Plant Master File ☐☐☐☐☐☐☐☐</td></tr>
<tr><td>Country/Name of Manufacturing Plant/Address</td><td>☐Country:
☐Name of Manufacturing Plant:
☐Address:</td></tr>
<tr><td>Description of Application [2]
(For each case, up to 2 dosage forms/products/operations may be applied for)
☐New Plant
☐Expansion
☐Addition of dosage form/product/operations</td><td>☐Orphan Drug ☐Sterile medicinal products ☐Biological medicinal products ☐Biological active substances ☐Blood products derived from human blood or human plasma
[□ Terminal Sterilization □ Aseptically Prepared: □SVP □LVP]
1._____
2._____</td></tr>
<tr><td>Specially Toxic & Hazardous Substances</td><td>The scope of this application includes:
□ Penicillins □ Cephalosporins □ Hormones □ Cytotoxics</td></tr>
<tr><td>Method of Application (Full/Simplified/Quote review)</td><td>
<table>
<tr><td></td><td>□ Non-sterile medicinal products</td><td>□ Sterile medicinal products</td><td>☐ Biological medicinal products/☐ Biological active 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 substitue the Docum</td><td>□</td><td>□</td><td>□</td></tr>
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<tr><td></td><td>
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<tr><td>ents of Validation and Qualification</td><td></td><td></td><td></td></tr>
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<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>
</table>
</td></tr>
<tr><td>Review fees</td><td>□ 1 dosage form/product/operation: NT$120,000 exactly
□ 2 dosage forms/products/operations: NT$140,000 exactly
□ Orphan drug: NT$4,000 exactly</td></tr>
<tr><td>Case numeration principle</td><td>1. Case numeration principles:
(1) First 3 digits ---Year code (fix data, applicant needs not fill in)
(2) 4th Digit --- new or old site (1: New; 2: Addition or expansion)
(3) 5th digit --- Type of manufacturing site for the dosage forms for application (1: Non-sterile medicinal products site, 2: Sterile medicinal products site, 3: Biological medicinal products site, 4: primary/secondary packaging site, 5: Others)
(4) 6th ~8th digits---Serial number [According to serial number record book]
2. 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</td></tr>
</table>

	manufacturing activity in GMP Determinations.

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

	Submission methods								
Forms that must be required	Non-sterile medicinal products (Including secondary packaging process)		Sterile medicinal products		Biological medicinal products /Biological active substances/ Blood products derived from human blood or 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 active 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 active 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 GMP inspection conducted by the local competent health authority (the scope of inspection to also include 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 Quote review, legalization of the dossier is not required.