Standards of Review Fees for the Registration of Orphan Drug Submitted to the Department of Health, Executive Yuan

Promulgated on December 28, 2000 (Unit：TWD)

Category	Definition and scope	Review fees	Remark
1. New drugs	New drug under The Rare Disease and Orphan Drug Act	10,000	New item
	Good Manufacturing Practice inspections for new establishment or addition of a new dosage form for domestic pharmaceutical manufacturer	4,000	New item
	Review of a Plant Master File for foreign pharmaceutical manufacturer	4,000	New item
2. Biological drugs, Anti-toxins, Bacterial solution and Gene-engineering biological products	Blood products, Anti-toxins, Vaccines, Gene-engineering biological products	10,000	New item
	Good Manufacturing Practice inspections for new establishment or addition of a new dosage form for domestic pharmaceutical manufacturer	4,000	New item
	Review of a Plant Master File for foreign pharmaceutical manufacturer	4,000	New item
3. Clinical trial	Investigational New Drug application	3,000	New item
4. Raw materials	Raw materials for manufacturers to manufacture orphan drugs	6,000	New item
5. Importing raw materials for their own use	Submission for importing raw materials for their own use	300	New item
6. New medical devices (including new effectiveness)	New medical devices that need to submit with clinical and safety test reports, etc.	6,000	New item
	Good Manufacturing Practice inspections for domestic medical device manufacturer	4,000	New item
	Review of a Plant Master File for foreign medical device manufacturer	4,000	New item
7. Post-approval change of drugs	Changes in new indication, new administration dosage, new category, new excipient	2,400	New item
	Changes in contract manufacturing, transfer, merger, place of production or manufacturing-site relocation (Applications of the change are limited to one manufacturing site per application)	1,600	New item
	Changes other than previous or reissue of the license, approved label or package insert	1,000	New item
8. Post-approval changes of medical	Changes of effectiveness, intended use or indication	2,400	New item

devices			
	Changes in contract manufacturing, transfer, merger, changes of production site or manufacturing site (Applications of the change are limited to one manufacturing site per application), changes of specification	1,600	New item
	Other changes or re-issuance of approved document of labels or instructions for the license	1,000	New item
9. Extension of an orphan drug license	Extension of an orphan drug license and certificate	600	New item
10. Free Sale Certificate、GMP certificate、Free Sale Certificate of medical device		300	New item
11. Collection of an orphan drug license		300	New item