attachment1

Drug registration fee standard

The State Drug Administration and the provincial drug regulatory authorities shall, in accordance with the law

Define responsibilities for drug clinical trial applications, drug marketing authorization applications, and supplementary applications

Administrative acceptance, on-site inspection/verification, technical review, etc. for re-registration applications

Book work, and charge relevant fees according to the standard. The specific charges are as follows:

Unit: ten thousand yuan

Types of section		Domestic production	Overseas production
New drug registration fee	Clinical Trials	19.20	37.60
	Marketing Authorization	43.20	59.39
Generic drug registration fee	No marketing authorization required for clinical trials	18.36	36.76
	Marketing authorization required for clinical trials	31.80	50.20
Supplementary application registration fee	without technical review	0.96	0.96
	subject to technical review	9.96	28.36
Drug re-registration fee (every five years)		by provincial prices, made by the finance department	22.72

Note: 1. The drug registration fee is charged according to one API or one preparation for one variety. If another specification is added, it will be charged according to the corresponding A 20% registration fee will be charged for each category.

2. In the "Administrative Measures for Drug Registration", it belongs to the record/report category change of the provincial drug supervision and administration department or the drug of the State Council No registration fee will be charged for the application items for filing/reporting changes by the supervision and management department.

3. For the one-time import of drugs (medicinal materials), a drug registration fee of 2,000 yuan will be charged according to one drug (medicinal materials).

4. The registration fees for drugs produced overseas shall be subject to domestic and overseas inspection traffic on the basis of the corresponding domestic registration fees. Fees, accommodation and meals, etc.

5. Hong Kong, Macao and Taiwan drug registration fee standard shall be implemented according to the overseas production drug registration fee standard.

6. The charging standards for expedited fees for drug registration shall be formulated separately.