

name, registered location, packing specification. ☐ Change of the location where the import drug is manufactured. ☐ Change of the location where the import drug is packed overseas. ☐ Repacking of import drugs in China. ☐ Change of the location where the raw material for import preparation is manufactured.

☐ Supplemental applications to be approved by PDA and be filed for record at SFDA, or directly be filed for record at SFDA: ☐ Change of the name of a domestic drug manufacturer. ☐ Internal change of the manufacture workshop of a domestic drug manufacturer. ☐ Change of immediate packing material or container (except for the item 10 as above) ☐ Change of valid period of domestic drugs ☐ Change of manufacture location of import drugs ☐ Change of appearance of the drug without change of drug standards. ☐ Amendment of insert sheet of the drugs according to national drug standards or required by SFDA. ☐ Supplementing and perfecting of the drug safety part of the insert sheet. ☐ Modification of design of packing and label of the drugs according to the regulation. ☐ Change of the agent for import drug registration. ☐ Others

☐ Supplemental applications to be filed for record at PDA: ☐ Amendment of insert sheet of the domestic drugs according to national drug standards or required by SFDA. ☐ Supplementing and perfecting of the domestic drug safety part of the insert sheet. ☐ Modification of design of packing and label of the domestic drugs according to the regulation. ☐ Change of the packing specification of domestic drugs. ☐ Change of manufacture location of domestic drugs ☐ Change of appearance of the domestic drug without change of drug standards. ☐ others

Drugs Information

6 Generic Name:

7 Generic Name Source:

8 English / Latin name:

9 Chinese Phonetic Alphabet:

10 Chemical Name:

10 Trade Names:

11 Product category:

12 strength:

13 Other accepted or submitted preparation and Strength at the same time:

14 Packaging: immediate packing material:

Packaging size:

15 Date of Expiration: 36 months

16 Prescriptions (Including Prescription Volume):

API/materials in TCM(Traditional Chinese medicine): _____

Accessories: _____

17 Materials /Accessories Source

Serial NO.	Materials /Accessories Name	Approval No/ Registration No/ Accepted No	Manufacturer	Implementation Standards	Variation or not	Variation approved status and approved institution
1						
2						

The Auction Law Of The Peoples Republic Of China Engchin Ed

Donald C. Clarke



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