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DRUG REGISTRATION REGULATION

Approval of Repackaging of Import Drugs

Article 1: Repackaging of import drugs means taking from offshore finished drug preparation in large packaging and putting them into smaller packaging, or taking drugs in smaller packaging and placing them into final (outside) packaging with an insert sheet, labeling, etc. in China.

Article 2: The application for repackaging of import drug shall comply with following requirements:

1) an *Import Drug Certificate* or *Pharmaceutical Product Certificate* has already been obtained for the import drugs;
2) the drug should not yet be manufactured in China or, if manufactured, not able to meet the clinical demand;
3) the drug of one pharmaceutical company shall only be repackaged by one pharmaceutical production enterprise, generally for a period not exceeding the valid period of *Import Drug Certificate* or *Pharmaceutical Product Certificate*.
4) The onshore pharmaceutical production enterprise shall have a *Drug Manufacturing License*. If the tablet with no packing or capsule is to be repacked in China, the drug to be repackaged shall be within the production scope described in its *Drug Manufacturing License* and *GMP Certificate*.
5) Any application for repacking of import drug should be made one year prior to expiration of *Import Drug Certificate* or *Pharmaceutical Product Certificate*.

Article 3: The offshore pharmaceutical company shall sign a *Repackaging Contract for Import Drugs* with an onshore pharmaceutical production enterprise, complete the *Drug Supplemental Application Form*.

Article 4: An application for repackaging a drug shall be submitted by the onshore pharmaceutical production enterprise to the PDA where the party is located, and the *Drug Supplemental Application Form* signed by the offshore pharmaceutical company should be submitted with the relevant information and sample products. PDA shall examine for form the application dossier, and if the requirements are met, the application will be accepted with issuing of acceptance notification of drug registration application. If the requirements are not met, the application will not be accepted with issuing of non-acceptance notification of drug registration application, with explanation of reasons.

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PDA should make recommendation after completion of the review process and submit the application dossier and recommendation to SFDA for approval, and notify the applicant.

Article 5: Upon receipt of the application dossier, SFDA shall review the submission. When SFDA consider the requirements are met, *Approval for Drug Supplemental Application* and Drug Approval Number will be issued. When SFDA does not consider the requirements are met, *Notification of Approval Opinion* will be issued with explanation.

Article 6: The registration standards for the import drug shall be applied to the repackaged drug.

Article 7: The package, label and insert sheet of a repackaged drug shall be consistent with that of the import drug to be repacked, and shall include the approval number for drug to be repacked and name of the drug repackaging manufacturer.

Article 8: The import inspection of finished drug preparations in large packaging should be conducted in accordance with SFDA regulations. The same standards shall be applied to both the inspection of the repackaged drug and import drug.

Article 9: The offshore pharmaceutical company shall be responsible for the quality of the repackaged drugs. If a quality problem arisen, SFDA may cancel the approval number of the drug repackaging, and if necessary, cancel the *Import Drug Certificate* or *Pharmaceutical Product Certificate* of the drug in accordance with Article 42 of *Drug Administration Law*.