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DRUG REGISTRATION REGULATION

Application and Approval for OTC Drugs

Article 1: An OTC drug means a drug designated by SFDA, for which consumers may purchase and use by own judgment without a prescription from a practicing physician or a practicing assistant physician.

Article 2: In the following circumstances, an applicant may apply for OTC drug registration, in making drug application:

1) the production and / or importation of OTC drugs already with national standards;
2) change in dosage form, but without change in indications, dosage, route of administration of an OTC drug as designated by SFDA;
3) new combination preparations developed from active OTC ingredients designated by SFDA.

Article 3: For a drug meeting the requirement of Article 119.1), applicant should check the OTC items in the "supplemental application item" of the *Drug Registration Form*. SFDA shall designate the drug as OTC in approving its registration. In the event of failure to check the OTC items in the *Drug Registration Form*, after SFDA approved the drug registration, applicant should proceed the registration according to the *Regulation of Categorized Administration of Prescription Drug and OTC Drugs* (temporary) and the provision of OTC registration.

Article 4: For a drug meeting the requirement of Article 119.2) or 3), applicant should check the OTC items in the "supplemental application item" of the *Drug Registration Form*. When SFDA consider the drug meet the OTC drug requirement, SFDA shall designate the drug as OTC in approving its registration. When SFDA does not consider the drug meet the OTC drug requirement, SFDA shall approve the drug as prescription drug. .

Article 5: Generally, for a drug meeting the requirement of Article 119.1) or 2), a clinical study is not needed. However, bioequivalence trials may be needed for solid oral dosage forms of drug. A clinical trial setout in this Regulation is needed for TCM preparation.

Article 6: For a drug meeting the requirement of Article 119.3), basis of formula should be explained, and if necessary, a clinical study is needed.

Article 7: OTC regulation should apply for OTC registration, drug insert sheet and packing as well as label. Prescription regulation should apply for other application information.

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Article 8: Import drug application and approval process should apply for application of import OTC drug, where technical requirement of import OTC drug should e the same of the domestic one.

Article 9: SFDA shall approve the re-registration application of import OTC drug based on the procedure of import drug re-registration application and approval process and OTC administration regulation. Applicant need not to complete OTC registration at PDA when applying the re-registration application of import OTC drug

Article 10: If an OTC drug has been approved by SFDA for marketing, but if during its use if discovered if is not suitable for use as OTC drug, SFDA can change the drug to prescription status.