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DRUG REGISTRATION REGULATION

Application and Approval for Import Drugs

Article 1: An import drug, for which application is made, shall have obtained marketing approval in its country/region of manufacture. An import drug without such a marketing approval may still be approved after SFDA confirms the safety and efficacy of the kind of drug, and there is a clinical need for the drug.

The drug for which import application is made shall meet the *GMP* standard in the foreign country / region as well as the requirements of *GMP* in China

Article 2: For an import drug application, the applicant shall complete *Application Form for Drug Registration* and submit the relevant application dossier and sample product and relevant certified documents. The application shall be made with SFDA.

Article 3: SFDA shall examine for form the application dossier, if the requirements are met, the application shall be accepted, and an acceptance notification shall be issued. SFDA shall notify NICPBP for drug registration inspection. When SFDA does not consider the requirements are met, Notification of Non- Acceptance will be issued with explanation. SFDA may organize the on-site inspection about the research status and manufacturing condition, if necessary.

Article 4: Upon completion of the drug inspection, NICPBP shall submit the verified drug standards, the drug inspection report and inspection recommendations to SFDA.

Article 5: SFDA shall conduct a comprehensive review of the application dossier submitted and if necessary SFDA may request the applicant to provide supplemental information. SFDA shall issue its decision of whether clinical study is approved through *Approval of Clinical Study of Drugs Form*. When SFDA does not consider the requirements are met, *Notification of Approval Opinion* will be issued with explanation

Article 6: Upon approval of the clinical study, the applicant shall conduct the clinical study in accordance with the provision under Chapter 4 of this *Regulation*.

Upon the completion of clinical study, the applicant shall, in accordance with relevant requirements, submit to SFDA the clinical study report, sample products, relevant changes and

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supplemental information, with detailed explanation and justifications, and the relevant certified documents.

Article 7: SFDA shall organize and conduct a comprehensive review of the submitted clinical study information and if necessary SFDA may request the applicant to provide supplemental information. If the requirements are met, issue an *Import Drug Certificate*. Regulation for import drug will apply for applicants from Hong Kong, Macao and Taiwan of China. If the requirements are met, a *Pharmaceutical Product Certificate* shall be issued to the When SFDA does not consider the requirements are met, *Notification of Approval Opinion* will be issued with explanation.

Article 8: For an import drug preparations application, documents to evidence the legal channels of immediate packaging materials or containers of the drug, documents to evidence the legal channels of drug raw material and supplemental material must be provided. For raw material and supplemental material of drug that has not been approved by SFDA, the information of relevant production processes, quality specification, and inspection methods should be submitted.

Article 9: SFDA shall simultaneously issue a registration standard and insert sheet in approving an import drug.