

Supplemental applications only need to be filed for *record* at the SFDA in the following situations:

1. Change in the name of a domestic drug manufacturer.
2. Internal change in the manufacturing company of a domestic drug manufacturer.
3. Amendment to the drug insert sheet according to national drug standards or required by the SFDA.
4. Supplementing and/or improving the drug safety section of the insert sheet.
5. Modification of the packing design and drug label according to regulations
6. Change in the packing specification for drugs manufactured domestically.
7. Change in validity period for drugs manufactured domestically.
8. Change in the location where the raw material for domestic preparation is manufactured.
9. Change in the drug appearance without changing drug standards.
10. Change in the import drug registration agent.

License renewal:

Import License will be valid for 5 years; renewal applications should be submitted 6 months prior to the product license expiration date. Post-marketing surveillance reports must be submitted with the renewal application.

Fast-track Review:

A fast-track application process is also available for designated drugs, such as:

1. Formulations made from plants, animals or minerals that have never been marketed in China or elsewhere. Newly discovered herbs and their preparations.
2. New chemical entities or biological products that have never been launched in any country.
3. New drugs to treat HIV, cancer and rare diseases (orphan drugs).
4. New drugs to treat diseases which still do not have effective therapeutic methods.
5. Requisite drugs to treat emergency healthcare events.

## **D. Application Documents for New Drug Registration**

The new drug registration application consists of 4 sections:

1. Summary materials
2. Pharmaceutical research materials
3. Pharmacological and toxicological research materials
4. Clinical research materials

For each section, the SFDA issued a detailed documents list for Chemical drugs, Biological products and Chinese Traditional Medicine. The SFDA also gives explanations in the appendices of the *Administrative Provisions for Drug Registration* for each document section. In addition, the SFDA issued technical guidance for some document sections. The document guidance is easy to follow during preparation. Usually for imported products, if the documents are prepared in accordance with ICH guidelines, the drugs will be accepted by the SFDA, even without the technical guidance.

Overall, during the registration process, pharmaceutical companies should not encounter problems with different data requirements in China and foreign countries. Since registration document requirements all follow ICH guidelines, requirements are fairly similar for China and the United States and the European Union. Problems often arise when a drug company does not want to submit sensitive, confidential data for drug registration in China. These companies are often reluctant to divulge information about the manufacturing process or quality control of raw materials. Drug companies registering a drug must discuss the case informally with experts from the Center for Drug Evaluation in order to find out what the minimum requirements are for their therapeutic area.

**For Chemical drugs, the full list of application documents includes the following 33 items:**

### Summary Materials:

1. Drug name.
2. Certified Documents (i.e. Drug Manufacturing License, GMP Certificate and patent status).
3. Drug discovery and current status of the drug including R&D and summary of the use of the drug both domestically and overseas.