

require approval from the provincial drug authority (PDA), or alternatively can just be filed for record (without approval) with the SFDA. The final 6 situations can be filed for record with the PDA.

A supplemental application needs to be approved by the SFDA in the following situations:

1. Application for Drug Approval Number of a new drug by the New Drug Certificate holder of the drug.
2. Application for use of a drug trade name.
3. Additional indications or functions of TCM or natural drugs, or the indications approved in China for chemical drugs or biological products.
4. Change in the usage or dosage of a drug, or the group of patients to use the drug, but without change in route of administration.
5. Change of strength of drug.
6. Change to supplementary (inactive) ingredients in the formula of the drugs, where there is a medical requirement for it.
7. A change in drug manufacturing technology and process that affects drug quality.
8. Amendment of drug registration standards.
9. Substitution or removal of drug material listed in National Drug Standards as toxic or endangered.
10. Change of immediate packaging material or container of import drugs, domestic injections, ophthalmological drugs, sprays, powder aerosols, or inhalers. Use of new immediate packaging material or container.
11. Application for combined packing of drug.
12. Transfer of new drug technology.
13. Addition or amendment of items in insert sheet of TCM or natural drug, such as pharmacology, toxicology, clinical trials, or pharmacokinetics.
14. Change in items within the import drug registration certificate, such as drug name, drug enterprise name, registered location, packing specification.
15. Change of location where imported drug is manufactured.
16. Change of location where imported drug is packed overseas.
17. Repacking of import drugs in China.

A supplemental application can be approved by the PDA or filed for record with the SFDA in the following situations:

**For Therapeutic Biological drugs, the full list of application documents includes the following 38 items:**

Summary Materials:

1. Drug name.
2. Certified Documents (Drug Manufacturing License, GMP Certificate, patent status, business licenses, etc.).
3. Drug discovery and current status of the drug including R&D and summary of the use and production of the drug both domestically and overseas.
4. Summary and evaluation of main research results including a comprehensive analysis of the safety, efficacy and quality controllability of the drug
5. Insert sheet, notes, and latest literature.
6. Design for packaging and label.

Pharmaceutical Research Materials:

7. Summary of pharmaceutical study information.
8. Research information about the raw materials used for production.
  - a. Research information about the sourcing, collection, and quality control of the animal or plant tissues or cells, or unprocessed blood plasma.
  - b. Research information about the sourcing, collection (or selection) process and determination of cells used for production.
  - c. Information about the establishment, determination, storage of the strain banks, as well as the stability of culture transfer.
  - d. Research information about the sourcing, quality control of other raw materials used for production.
9. Research information about the production process for the raw materials or unprocessed fluids.
10. Research information about the formula and process for the preparations, sourcing and quality standards of supplements, and relevant literature.
11. Experiment information and literature about product quality, including the preparation and standardization of the standard material or controls, as well as comparisons with similar products already marketed domestically or overseas.