appendix

Chemical drug registration classification and application data requirements

1. Classification of chemical drug registration

The registration classification of chemical drugs is divided into innovative drugs, improved new drugs, generic drugs, overseas Listed domestic unlisted chemical drugs are divided into the following 5 categories:

Category 1: Innovative drugs that have not been marketed at home and abroad. Refers to a new structure with a clear Compounds with pharmacological effects and drugs with clinical value.

Category 2: Improved new drugs that have not been marketed at home or abroad. Refers to the known active ingredient On this basis, the structure, dosage form, prescription process, route of administration, indications, etc. Optimized medicines with clear clinical advantages.

2.1 Optical products containing known active ingredients prepared by methods such as resolution or synthesis Isomers, either esters of known active ingredients, or salts of known active ingredients (including (including salts containing hydrogen bonds or coordination bonds), or changing the acid group of known salt active ingredients, bases or metal elements, or form other non-covalent derivatives (such as complexes, chelates compounds or clathrates) and have obvious clinical advantages.

2.2 New dosage forms (including new drug delivery systems) containing known active ingredients, new locations Drugs with obvious clinical advantages and prescription technology, new routes of administration.

2.3 New compound preparations containing known active ingredients with obvious clinical advantages.

2.4 Drugs for new indications containing known active ingredients.

Category 3: Drugs that are imitated by domestic applicants and marketed overseas but not marketed in China

Taste. Such drugs should be of the same quality and efficacy as the reference preparation.

Category 4: The domestic applicant imitates the original drug that has been marketed in China. this class

The medicinal product should be of the same quality and efficacy as the reference preparation.

Category 5: Drugs marketed overseas apply for domestic marketing.

5.1 The original research drugs and improved drugs marketed overseas shall apply for domestic marketing. change

Good drugs should have obvious clinical advantages.

5.2 Generic drugs marketed overseas shall apply for listing in China.

The original research drug refers to the first drug approved for marketing at home and abroad, and has a complete and sufficient safety profile.

Drugs for which comprehensive and efficacy data are used as the basis for marketing.

Reference preparation refers to the development of generic drugs that have been evaluated and confirmed by the national drug regulatory authority.

Control drug used. The selection and publication of reference preparations shall be conducted in accordance with the national drug regulatory authorities.

Implement relevant regulations.

2. Relevant registration management requirements

(1) Class 1 chemical drugs are innovative drugs, which should contain new

Compounds with pharmacological effects and clinical value, excluding those in improved new drugs

Drugs of class 2.1. containing novel, well-defined, pharmacologically active compounds

New compound preparations shall be declared in accordance with Category 1 of chemical drugs.

(2) Class 2 chemicals are improved new drugs, based on known active ingredients

For optimization, it should have obvious clinical advantages than before improvement. Known active ingredients refer to domestic

Or the active ingredients of overseas marketed drugs. This type of drug meets the requirements of multiple situations at the same time

If yes, it must be stated in the declaration.

(3) Class 3 chemical drugs are imitations produced in China and have been marketed overseas and have not been listed in China

The medicines of the city's original research medicines have the same active ingredients, dosage forms, specifications as the reference preparations.

Qualifications, indications, route of administration and usage and dosage, and demonstrate the quality and efficacy with the reference system

Dosage is the same.

When justified by adequate research data, strengths and dosages may be

Inconsistent with the reference preparation.

(IV) Category 4 chemical drugs are domestically produced generic drugs that have been marketed in China

medicines with the same active ingredients, dosage forms, specifications, indications,

route of administration, usage and dosage, and prove that the quality and efficacy are consistent with the reference preparation.

(5) The 5 categories of chemical drugs that are listed overseas are applied for domestic listing, including

Including medicines produced at home and abroad. Among them, chemical drugs 5.1 are original research drugs and modified drugs

Drugs, modified drugs are optimized on the basis of known active ingredients, and should be better than those before modification.

It has obvious clinical advantages; chemical drugs 5.2 are generic drugs, which should be proved to be in line with the reference system.

The quality and efficacy of the drug are the same, and the technical requirements are the same as those of Class 3 and Class 4 chemicals. territory

Generic drugs produced overseas that are simultaneously researched and developed should be declared in accordance with Category 5.2 of chemical drugs, such as

To apply for a clinical trial, it is not required to provide documents that allow the drug to be marketed.

(VI) For the listed drugs, the indications that have been approved overseas and not approved in China shall be added according to the

Drug clinical trials and marketing authorization application channels are used for declaration.

(7) During the review and approval of drug marketing applications, drug registration classification and technical requirements

It is required that there will be no changes due to the approval of the marketing of preparations with the same active ingredients both at home and abroad. drug

The registration classification is determined at the time of filing the listing application.

3. Requirements for application materials

(1) The applicant proposes drug clinical trials, drug marketing registration and chemical raw materials

Drug applications should be in accordance with the relevant technical guidelines published by the national drug regulatory authorities.

To carry out research according to relevant requirements, and follow the current version of "M4: General Application for Registration of Drugs for Human Use"

Technical Document (CTD)" (hereinafter referred to as CTD) format number and item order

and submit the application materials. Items that are not applicable may be reasonably absent, but should be marked as not applicable and

Explain why.

(2) When applying for drug marketing registration after completing the clinical trial, the applicant shall

Submit an electronic clinical trial database on a CTD basis. Database formats and related

For specific requirements such as documents, please refer to the relevant guidelines for clinical trial data submission.

(3) The Center for Drug Evaluation of the State Food and Drug Administration will, according to the needs of drug evaluation work, combine

Revision of ICH technical guidelines, timely update of CTD documents and on the central website

release.