appendix

Review and approval procedures for overseas new drugs that are urgently needed for clinical use

In order to implement the spirit of the State Council executive meeting on June 20, according to the General Office of the CPC Central Committee "Opinions of the General Office of the State Council on Deepening the Reform of the Review and Approval System and Encouraging Innovation of Drugs and Medical Devices" (Ting Zi [2017] No. 42), "Opinions of the Food and Drug Administration on Encouraging Drug Innovation to Implement Prioritized Review and Approval" (CFDA According to relevant regulations such as Pharmaceutical and Chemical Administration [2017] No. 126), the State Food and Drug Administration and the National Health Commission have established special channels to review and approve overseas new drugs that are urgently needed for clinical use. Now The working procedures are announced as follows:

1. Scope of varieties reviewed and approved by special channel

New products that have been launched in the United States, the European Union or Japan in the past ten years but have not been launched in my country Drugs that meet one of the following conditions:

(1) Drugs used to treat rare diseases; (2) Drugs used to prevent and treat serious life-threatening diseases for which there is no effective treatment or prevention Means of medicine;

(3) Used to prevent and treat serious life-threatening diseases and have obvious clinical advantages drug.

2. Variety selection

The State Food and Drug Administration and the National Health Commission regulate around, organize and carry out variety selection. The selection work adheres to the clinical value-oriented and abides by Following the principles of openness, fairness and impartiality, the specific procedures are as follows:

(1) Preliminary screening. The Drug Evaluation Center of the State Drug Administration (hereinafter referred to as the Drug Evaluation Center)

organized experts to sort out new drugs that have been marketed in the United States, the European Union, and Japan in the past ten years but have not been

marketed in my country, and initially screened out those that meet the requirements of this procedure.

List of species requested.

(2) Expert argumentation. The State Food and Drug Administration and the National Health Commission convened an expert demonstration meeting

to discuss the preliminary screening list of varieties.

Experts' opinions are used to select a list of varieties that meet the requirements of this procedure.

(3) Public announcement. The Center for Drug Evaluation will publish the list of selected varieties to the public. If you raise objections to the published

varieties, you should submit written opinions to the Center for Drug Evaluation within 5 days and

Give reasons. For objectionable varieties, a decision will be made after separate organization and demonstration, and all relevant parties will be notified.

Guan Fang.

(4) Announcement. The Center for Drug Evaluation of the National Medical Products Administration released the

List of varieties approved by the gate channel review.

3. Review and Approval Procedure

Any product that is included in the list of varieties reviewed and approved by special channels must be approved in the United States, the European Union or Japan.

If this first-time licensed business study finds that there are no racial differences, you can proceed as follows:

Procedure to carry out registration work:

(1) Communication. Applicants should follow the "Drug Research and Development and Technical Review and Approval"

The "Measures for the Management of Communication and Exchange" requires that an application for a Class I meeting be made to the Center for Drug Evaluation.

(2) Application. If a consensus is reached after communication, the applicant shall declare

Document requirements (see attachment) Prepare documents and submit application based on the following circumstances:

1. For varieties that have not submitted clinical or marketing applications before the release of this procedure, applicants can

Submit a marketing application to the Center for Drug Evaluation.

2. Varieties that have submitted clinical applications before the release of this program but have not yet completed technical review.

The applicant may submit a written application to the Center for Drug Evaluation to adjust the clinical application to a marketing application.

Please submit all research materials obtained overseas and supporting evidence that there are no racial differences.

Material.

3. For varieties that are undergoing clinical trials, applicants may submit applications to the Center for Drug Evaluation.

The city applied for and continued to advance clinical trials. After completing the clinical trial, the applicant should supplement

Submit the research report to the Center for Drug Evaluation in the form of a recharge application.

4. For varieties that have submitted marketing applications before the release of this procedure, applicants can apply to the Drug Evaluation Center

Please replenish all research materials obtained overseas and supporting materials that do not contain racial differences.

fee.

5. It has been listed in Japan or Hong Kong, Macau and Taiwan, and has sufficient clinical experience

For drugs that have been used in cases, the applicant should provide research on drug usage in the above-mentioned countries and regions.

Research reports and relevant analysis will be conducted, but research data on racial differences may not be provided for the time being.

6. Applicants should submit application documents to the China Institute of Food and Drug Control simultaneously as required.

Relevant information on drug standard review and testing, samples for testing, reference materials, and experiments

Materials etc. Specific requirements will be formulated separately by the China Institute for Food and Drug Control.

(3) Review. The Center for Drug Evaluation has established a special channel to carry out review and review of treatments for rare diseases.

For therapeutic drugs, the technical review must be completed within 3 months after acceptance; for other overseas new drugs,

The technical review will be completed within 6 months after acceptance. The above time limit does not include the applicant's supplementary

The time occupied by the data.

If the applicant needs to supplement information during the review period, the company can be notified during the professional review stage.

Supplementary information for the industry; Applicants can also submit on a rolling basis after communication

Information is provided through the applicant window in a timely manner.

(4) Approval. After receiving the review submitted by the Center for Drug Evaluation, the National Medical Products Administration

The approval decision will be made 10 working days after the nuclear materials are collected.

4. Work requirements

(1) Overseas new drug applicants should formulate risk management and control plans, promptly report adverse reactions, assess risk

situations, propose improvement measures, and conduct review of marketed drugs.

Conduct ongoing research and complete relevant research work in accordance with approval requirements.

(2) Application for products produced before obtaining my country's import drug approval documents

Please ensure that the product production process and registration standards are verified by the State Food and Drug Administration

On the premise that the specified technology and standards are consistent, import is allowed and inspection is carried out in accordance with the law.

(3) After the National Medical Products Administration completes the marketing approval, it can conduct clinical trial data verification according

to the needs of technical review. At the same time, post-marketing adverse reaction surveillance will be strengthened.

Test and re-evaluate. Drugs that have been confirmed to have serious adverse reactions can be discontinued.

Emergency control measures for sales and use.

Attachment: Application information requirements

attached

Application information requirements

In the past ten years, it has been listed in the United States, the European Union and Japan but has not yet been launched in my country.

For new drugs, it is planned to use overseas research data and carry out review and approval procedures according to special channels.

When applying for import registration, the specific requirements for declaration materials are as follows:

1. Supporting documents

Provide supporting documentation for marketing approval from drug regulatory agencies in the United States, the European Union and Japan

file; provide that the drug has been launched in one of Japan, Hong Kong, Macau, Taiwan and other regions

supporting documents, as well as the quantity of drugs exported to the region in the past five years and relevant certificates

explicit documents.

2. Common Technical Document (CTD) requirements for pharmaceuticals for human use

Applicants should strictly follow the International Conference on Harmonization of Technology for the Registration of Pharmaceuticals for Human Use (ICH)

The CTD format requires submission of application materials. Application materials should be submitted to the supervisory authority of developed countries.

The contents of the regulatory agencies are basically the same, and the research data accumulated after listing should be submitted.

Among them, the key research on the M1 module, M2 module and M3-M5 module in the CTD file is

The abstract of the research report should be in Chinese, with the original text attached for reference. medicine provided

Product instruction manual, the content is the same as the instruction manual approved and issued by the original listing country, and the format is

Follow the requirements of the "Provisions on the Administration of Drug Inserts and Labels" (State Food and Drug Administration Order No. 24).

3. Racial sensitivity analysis report

Applicants should refer to relevant ICH guidelines to identify Chinese and/or Asian populations and European

Conduct consistency analysis on efficacy and safety in beauty population.

4. Post-marketing research and post-marketing risk control plan

Applicants should base their research on overall efficacy and safety evaluation, as well as racial sensitivity analysis Analyze the situation and decide whether to conduct post-marketing clinical trials and formulate post-marketing risk control scientific judgment on the planning plan and provide necessary post-marketing research plans and specific clinical trials testing plan and post-marketing risk control plan.

5. Declaration of consistency of application materials

The applicant should declare that the application materials for import in China should be the ones used when applying for listing. All information submitted to foreign regulatory agencies and relevant studies completed after listing material.