appendix

药品注册申请审评期间变更工作程序
（试行）

In order to standardize changes during the review period of drug registration applications and ensure the safety of drugs

Complete, effective and quality controllable, according to the "Drug Administration Law of the People's Republic of China"

"Vaccine Administration Law of the People's Republic of China" "Drug Administration Law of the People's Republic of China"

Regulations for the Implementation of the Law, "Measures for the Administration of Drug Registration" and "Drug Production Supervision and Administration"

This procedure is formulated in accordance with the Measures and other laws, regulations and rules.

1. Scope of application and basic requirements

(1) During the review period of the drug marketing authorization application, an incident that may affect the drug

If there are major changes in safety, effectiveness and quality controllability, the applicant shall withdraw

Return to the original registration application and re-apply after supplementary research. Drug clinical trial application,

Drug marketing authorization applications, supplementary applications and re-registration applications for overseas-produced drugs, etc.

Other changes that occur during the technical review period apply to this procedure.

(2) In order to ensure the quality and efficiency of the review, during the review period, the applicant or drug

Changes proposed by the product marketing authorization holder shall not affect the technical aspects of the original application.

review.

(3) If changes really need to be made during the review period of the drug marketing registration application, it is encouraged to

Applicants are encouraged to communicate with the Center for Drug Evaluation in advance.

2. Changes and working procedures

(1) Review of drug clinical trial applications and supplementary applications during clinical trials

Changes during the review period

1. Change of applicant's name (excluding change of subject), change of registered address and

If the change of registered agency does not involve technical review content, the applicant should

The professional review status of the application (the current status of the variety review progress in the applicant's window

Displayed as "under professional review") notify the Center for Drug Evaluation in writing and submit relevant certification

Information, such as business license before and after the change, etc., and stamped with the applicant or registered agent

The official seal of the organization.

If the registered agency is changed, the overseas applicant shall also submit the original reasons for the cancellation.

Documents for the entrustment-agent registration relationship and new entrustment documents, and submit notarized documents and

Chinese translation.

2. During the review period of drug clinical trial application, changes in the applicant's subject and

Changes involving technology.

(2) Changes during the review period of drug marketing authorization application

1. If only the main body of the drug registration applicant changes, the transferee shall report to the drug registration applicant

The review center submits a supplementary application. This application is related to a drug marketing authorization application.

It will be submitted to the Bureau for review and approval, and the review time limit for the original marketing authorization application will remain unchanged.

During the review of the drug marketing authorization application, the main body of the drug registration applicant

If there is a change, the applicant after the change shall bear the corresponding responsibilities and ensure drug registration.

The information in the entire declaration process is true, accurate, complete and traceable.

Application materials refer to the "State Food and Drug Administration's Notice on Post-marketing Changes to Drugs"

Compiled in Annex 4 of the Announcement of Management Measures (Trial Implementation) (No. 8, 2021),

If there is no relevant information for the corresponding item, you can indicate "not applicable" under the item and explain the reason.

The application materials must also include the "Drug Registration Form" filled out by the drug registration applicant before and after the change.

Confirmation of change of product registration applicant (see attachment).

Among them, for drugs produced within the country, the drug registration applicant and

The corresponding "Drug Production License" of the manufacturing enterprise and its change record page; overseas

For drugs produced, a "Confirmation Letter of Change of Drug Registration Applicant" should also be submitted.

Notarized and certified documents, with Chinese translation attached.

2. If a technical change occurs, the classification and technical requirements of the change items shall refer to the

Implementation of relevant guiding principles for changes to marketed drugs.

Major events that may affect drug safety, effectiveness and quality controllability occur

If there is a change, the applicant should withdraw the original registration application and re-apply after supplementary research.

In the event of other changes involving technology other than major changes, the applicant should

When a supplementary application is filed in the professional review status of the original registration application, the supplementary application

Review related to the original registration application. If the supplementary application submitted is reviewed and confirmed to be

If there are major changes, the supplementary application will not be approved, and the applicant should withdraw the original application.

Apply for registration and re-apply after supplementary research.

If the review conclusion is not in line with the applicant's expectations, the applicant may refer to the "Drug Notes"

"Procedure for Resolution of Objections to Book Review Conclusions (Trial)".

Supplementary application materials should refer to the listed traditional Chinese medicines, chemical drugs and biological products.

Arrangement of changes in items and application materials requirements.

3. Other drug registration approval documents not involving technical review and

If the information stated in the attachment is changed, the applicant shall promptly notify the Center for Drug Evaluation in writing.

And submit relevant supporting documents, such as business licenses and production licenses before and after the change.

Certificate and its change record page, etc., stamped with the official seal of the applicant or registered agent.

If the registered agency is changed, the overseas applicant shall also submit the original reasons for the cancellation.

Documents for the entrustment-agent registration relationship and new entrustment documents, and submit notarized documents and

Chinese translation.

(3) Review of post-marketing supplementary applications and re-registration applications for overseas-produced drugs

Changes during the period

During the review period for post-marketing supplementary applications and re-registration applications for overseas-produced drugs

Changes shall be implemented in accordance with the "Measures for the Management of Post-Marketing Changes of Drugs (Trial)".

If a supplementary application is submitted during the review period, the applicant can specify in the registration application form

The declaration matters clearly indicate whether a review related to the variety under review is required.

3. Others

(1) The charging standard for supplementary applications during the review period shall refer to the "State Food and Drug Administration

Announcement on Re-issuing Drug Registration Fee Standards (No. 75, 2020)

Wait for the request to be executed.

(2) If the production site changes during the review process of the listing application, the applicant

The impact of the site change on the preparation needs to be evaluated, and the associated changes caused by

Shapes are judged in accordance with relevant guiding principles.

(3) After the varieties are linked, the time limit for review of the linked varieties shall remain consistent to ensure

Applications with more time remaining will be counted.

(4) Changes in raw materials during the review period shall refer to the relevant requirements for changes in preparations.

Ask for management.

(5) For changes that can be notified by letter, the applicant may send a written letter

Or submit official documents electronically through the applicant window.

(6) During the review stage of drug registration application, the applicant/holder can

Submit stability study data to industry review status.

(7) This working procedure shall come into effect from the date of issuance.

Attached: Confirmation of change of drug registration applicant

attached

药品注册申请人变更确认书

National Medical Products Administration:

For drug marketing authorization application (drug name) (acceptance number), the drug

Applicants for product registration shall be _____ Change to _____ . change

The final applicant shall bear corresponding responsibilities and ensure the information of the entire process of drug registration and application.

True, accurate, complete and traceable. After the drug marketing authorization application is approved,

The registered applicant after the change is the marketing authorization holder.

Drug registration applicants before/after the change:

(Signed by the legal representative or stamped with official seal)

date: