Procedures for Handling Filing-based Post-approval Changes for Drugs Manufactured Outside China [1]

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Pursuant to the *Provisions for Post-approval Changes of Drugs (Interim)*, the Center for Drug Evaluation (CDE) of the National Medical Products Administration has organized the formulation of the *Procedures for Handling Filing-based Post-approval Changes for Drugs Manufactured Outside China*.

In accordance with the requirements of the *Notice of the NMPA Comprehensive Department on Issuing the Procedures for Publication of Drug Technical Guidance*, and upon review and approval by the National Medical Products Administration, the Procedures are hereby issued and shall take effect as of the date of issuance.

Pursuant to the *Provisions for Post-approval Changes of Drugs (Interim)*, the Center for Drug Evaluation has formulated the *Procedures for Handling Filing-based Post-approval Changes for Drugs Manufactured Outside China*, in order to further clarify the handling procedures and requirements.

1. Scope of Products

Drugs manufactured outside China (including drugs manufactured in Hong Kong, Macao, and Taiwan; for drugs manufactured in Hong Kong and Macao, if there are separate provisions, they shall be implemented in accordance with the relevant requirements of the National Medical Products Administration).

2. Handling Procedures

(1) The Marketing Authorization Holder (hereinafter referred to as the "MAH") shall submit filing materials (in electronic form) through the NMPA's Drug Business Application System in

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accordance with the *Drug Registration Administration Measures* and the *Provisions for Post-approval Changes of Drugs (Interim)*, and obtain a filing number.

(2) Within 5 working days from the completion of filing, the National Medical Products Administration shall publicly disclose the filing information, which may be queried through the "Public Disclosure of Filing Information for Drugs Manufactured Outside China" section on the NMPA website.

(3) Within 30 working days from the completion of filing, Center for Drug Evaluation shall complete the review of the filing materials, the review opinion may be queried through the "Public Disclose of Filing Information for Drugs Manufactured Outside China" section on the NMPA website.

3. Work Requirements

(1) The MAH shall, in accordance with the relevant technical guidelines, determine the change management category of the drugs manufactured outside China.

(2) The Marketing Authorization Holder (MAH) shall prepare the filing materials with reference to the relevant requirements set forth in the *Technical Guidelines for Pharmaceutical Changes of Marketed Traditional Chinese Medicines, Chemical Drugs, and Biological Products* and the *Technical Guidelines for Clinical Changes of Marketed Chemical Drugs and Biological Products*, among others, and shall ensure the completeness and accuracy of the filing materials.

All information in the application form shall correspond to the publicly disclosed filing information. The MAH shall complete all items in the application form fully and accurately, so as to ensure the accuracy of the publicly disclosed filing information.

(3) Upon examination, if it is determined that the studies and validation results for the filing-based change already implemented by the marketing authorization holder are insufficient to demonstrate the scientific soundness, reasonableness, and controllability of risks of the change, or that the classification of the change management category is improper, the marketing authorization holder shall rectify the deficiencies in accordance with the review opinions.

(4) Where drugs manufactured outside China are no longer produced in the form of sub-packaging, and the marketing authorization holder applies for cancellation of the filing, or where the National Medical Products Administration requires that the filing be cancelled, the

marketing authorization holder shall promptly report to the Center for Drug Evaluation for cancellation of the relevant filing

(5) Drug substances that have been registered on the API, Excipient and Packaging Material Registration Platform shall be implemented with reference to this provision.

(6) This procedure shall come into effect from the date of its issuance.