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Turkish Pharmaceuticals and Medical Devices Agency updated the Guidelines for the Classification of Diversification Applications and Variation Applications

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Turkish Pharmaceuticals and Medical Devices Agency ("**TITCK**")'s Guidelines for the Classification of Diversification Applications and Variation Applications Within the scope of the Guideline, it is aimed to help the classification of applications by comparing diversification applications with variation applications, you can access our article on the Guideline through this link.

On 06 March 2023, the Guideline was updated and published on the T?TCK website.

Within the scope of the update, the process for companies that request the cancellation of the old marketing authorization with a diversification application and the process after obtaining the marketing authorization have been added. In this context, companies requesting a license with a diversification application must first obtain CTD Preliminary Examination approval in case of a request for cancellation of the old license. After the old marketing authorization is cancelled and the new marketing authorization is issued, it will be allowed to produce and market the products with barcodes belonging to the old marketing authorization with the same barcode for a period of six months and the control procedures will be carried out through the Pharmaceutical Tracking System.

As a result of the update, the applications for change of packaging volume without changing the quantity under the heading "Solution for injection" in the sample table have been changed as diversification applications.

You can access the full text of the Guideline through this link.

Related Practices

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