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# Overview of Specifications for Evaluating Efficacy Description of Cosmetics

Corporate legal flash

April 2021



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## Summary

On April 8, 2021, the National Medical Products Administration (“**NMPA**”) published the Specifications for Evaluating Efficacy Description of Cosmetics (“**Specifications**”), effective May 1, 2021.

The Specifications aim to provide detailed guidelines for the efficacy evaluation of cosmetics.



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## Overview of Specifications for Evaluating Efficacy Description of Cosmetics

On April 8, 2021, the National Medical Products Administration (“NMPA”) published the Specifications for Evaluating Efficacy Description of Cosmetics (the “Specifications”), effective May 1, 2021.

The Specifications aim to provide detailed guidelines on the responsibilities of cosmetics registrants and record-filing applicants for cosmetic efficacy descriptions under the Regulations on the Supervision and Administration of Cosmetics. This legal flash summarizes the highlights of the Specifications.

### Highlights

#### General requirements

- The efficacy description of all cosmetics manufactured or operated in the territory of the People’s Republic of China (“China”) must be evaluated using methods that are scientific, reasonable, feasible and suitable for the purpose of evaluating the efficacy description of cosmetics.
- Under the Specifications, the evaluation of the efficacy description of cosmetics refers to the process of scientifically testing and reasonably evaluating the efficacy description of cosmetics under normal use conditions and making corresponding evaluation conclusions.

#### Parties responsible for evaluating the efficacy description of cosmetics

- The registrants and record-filing applicants of cosmetics will be responsible for evaluating the efficacy description, including:
  - Evaluating the efficacy description of cosmetics themselves or engaging a competent third-party institution
  - Uploading the abstract of the basis for the efficacy description of cosmetics on the NMPA’s designated website;<sup>1</sup>
  - Being responsible for the scientificity, authenticity, reliability and traceability of the abstract of the basis for efficacy description uploaded on the NMPA’s designated website; and
  - Filing the basis for the efficacy description of cosmetics and its abstract in a timely manner, and properly keeping it for future reference.

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<sup>1</sup>Currently the NMPA has not published the website yet for uploading the required abstract.



## Methods of evaluating the efficacy description of cosmetics

- According to the Specifications, efficacy description evaluation of cosmetics can be carried out by:
  - Researching the literature materials
  - Analyzing research data
  - Conducting cosmetic efficacy description evaluation tests, which include human efficacy evaluation tests, consumer use tests and laboratory tests
  - Others.

The Specifications establish the evaluation methods applicable to different efficacy descriptions of cosmetics. For example, the human efficacy evaluation test must be carried out when evaluating the efficacy description of cosmetics with sunscreen effects, which must be carried out by an inspection institution qualified for cosmetics registration and record-filing in China following the requirements of the mandatory national standards and the technical specifications, with the report issued accordingly.

The Specifications also provide technical guidelines and the applicable methods for the evaluation tests for efficacy description of cosmetics, as well as the requirements of laboratory practices and issuance of reports by institutions evaluating the efficacy description of cosmetics.

## Timeline

- Considering that certain cosmetics have been registered or filed, for the purpose to be manufactured and operated in China without relevant efficacy description evaluation in place, when promulgating the Specifications, the NMPA also issued an announcement, setting up a schedule for registrants and record-filing applicants of cosmetics to carry out their duties of evaluating the efficacy description of cosmetics and uploading its abstract, as follows:

Date of cosmetics registration/record-filing	Date of evaluation and uploading
Before May 1, 2021	Before May 1, 2023
From May 1, 2021, to December 31, 2021	Before May 1, 2022
From January 1, 2022	When applying for registration or record-filing of cosmetics



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