



Working Rules for Cosmetic Registration and Filing Testing

《化妆品注册和备案检验工作规范》

China National Medical Products
Administration

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Translated by ChemLinked

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Announcement of the National Medical Products Administration on Issuing and Implementing Working Rules for Cosmetic Registration and Filing Testing

(No. 72, 2019)

In order to regulate the testing for registration and filing of cosmetics and ensure that the testing work for registration and filing of cosmetics is open, fair, impartial and scientific, the National Medical Products Administration has formulated the "Working Rules for Cosmetic Registration and Filing Testing" (hereinafter referred to as the "Working Rules"), which are hereby promulgated and the relevant issues concerning the implementation are announced as follows:

1. From the date this announcement was promulgated, the inspection and testing institution that meets the requirements of the "Working Rules" can undertake the testing work for registration and filing of cosmetics after submitting relevant information of the inspection and testing institution through the testing information management system for registration and filing of cosmetics.
2. From the date this announcement was promulgated, the newly registered or filed cosmetics that have not yet been tested, shall be tested in accordance with the requirements of the "Working Rules" and the testing report shall be issued; if the test has been carried out or the overseas laboratory has completed the sun protection test and the testing report has been issued, the testing report may continue to be used for registration or filing of cosmetics. For products that have been registered or filed, if the original testing items are inconsistent with the "Working Rules", the test of corresponding test items shall be completed additionally within one year after the announcement was promulgated, in accordance with the requirements of the testing items specified in the "Working Rules" (except for the human safety testing items). The supplementary testing report shall be submitted when applying for extension of the validity period of the administrative license for the product, or provided for future reference when the product is filed and confirmed to continue production.
3. Since November 1, 2019, the relevant qualifications of the cosmetics administrative license testing institution or the domestic non-special use

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Working Rules for Cosmetic Registration and Filing Testing

cosmetics filing testing institution that has previously obtained the qualification accreditation or designation by the original China Food and Drug Administration shall automatically terminate, and the relevant testing institution must not continue to accept testing for registration or filing of cosmetics in the name of the originally accredited or designated qualification.

It is hereby announced.

Attachment: Working Rules for Cosmetic Registration and Filing Testing

National Medical Products Administration

September 3, 2019

Working Rules for Cosmetic Registration and Filing Testing

Article 1 In order to regulate the testing for registration and filing of cosmetics and ensure that the testing for registration and filing of cosmetics is open, fair, impartial and scientific, the Working Rules are formulated in accordance with the provisions of relevant regulations on cosmetics.

Article 2 The Working Rules apply to the inspection and testing work related to cosmetics registration and filing within the territory of the People's Republic of China, such as microbiological and physicochemical tests, toxicological tests, and human safety and efficacy evaluation tests.

Article 3 The cosmetic enterprise shall, in accordance with the requirements of regulations, mandatory national standards and specifications, select the inspection and testing institution with corresponding testing capabilities to test cosmetics of which registration or filing is applied for, and shall be responsible for the authenticity and integrity of the testing samples and relevant materials provided by them.

The inspection and testing institution engaged in testing for registration and filing of cosmetics (hereinafter referred to as the inspection and testing institution) shall carry out inspection and testing in accordance with the requirements of regulations, mandatory national standards and specifications, follow the principles of independence, objectivity, impartiality, openness and integrity, and be responsible for the authenticity and reliability of the testing report issued by them.

Article 4 The National Medical Products Administration shall organize to establish the testing information management system for registration and filing of cosmetics (hereinafter referred to as testing information system) for the management of testing for registration and filing of cosmetics and the information management of the inspection and testing institution.

Article 5 The inspection and testing institution shall generally have the independent legal person status. The inspection and testing institution without independent legal person status shall be authorized by the legal entity to which they belong, be able to independently undertake impartial testing as the third party and independently carry out inspection and testing business activities.

Before carrying out the testing for registration and filing of cosmetics, the

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