



Standards for the Management of Cosmetic Sampling Inspection (Draft for Comments)

化妆品抽样检验管理规范(征求意见稿)

National Medical Products Administration

Release Date: Sep.28, 2020

Implementation Date: XXXX-XX-XX

Translated by ChemLinked

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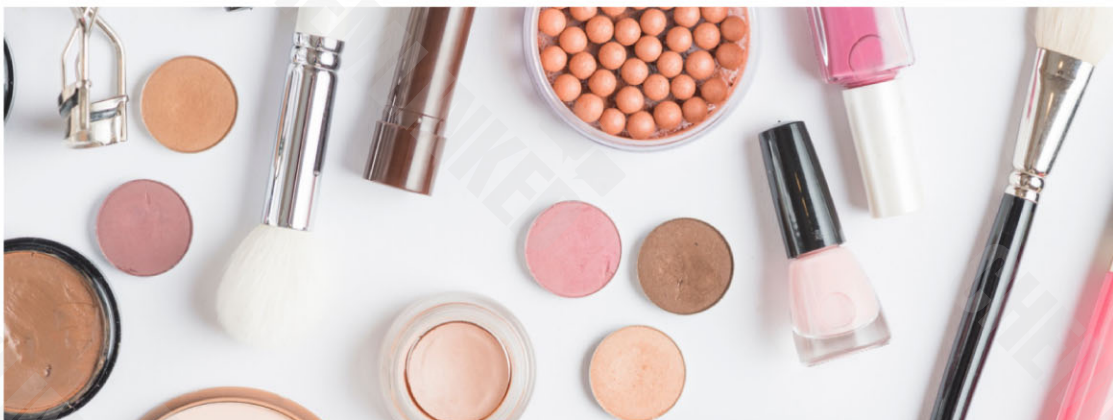
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Standards for the Management of Cosmetic Sampling testing (Draft for Comments)

Chapter I General Rules

Article 1 Legal Basis In order to strengthen the supervision and administration of cosmetics and standardize the sampling testing of cosmetics, this Standard is formulated in accordance with the *Cosmetic Supervision and Administration Regulation*, the *Supervision and Administration Measures on Cosmetics Manufacture and Operation* and other regulations.

Article 2 Scope of Application This Standard shall apply to the cosmetic sampling testing (hereinafter referred to as the sampling testing) involved in the production and operation of cosmetics by the department responsible for medical products supervision and administration within the territory of the People's Republic of China.

Article 3 Management Responsibilities The National Medical Products Administration (hereinafter referred to as the NMPA) is responsible for organizing and carrying out national sampling testing.

The provincial medical products administration department is responsible for organizing and implementing national sampling testing within its administrative area, and is responsible for organizing provincial sampling testing within its administrative area.

The departments responsible for medical products supervision and administration of the people's governments of cities and counties shall implement national and provincial sampling testing in accordance with the arrangement of higher-level departments.

For cosmetics that may have quality and safety risks found in complaint reporting, supervision and inspection, adverse reaction monitoring, and risk monitoring, the department responsible for medical products supervision and administration at or above the county level may conduct special sampling testing.

Article 4 Responsibilities of Testing Institutions National Institutes for Food and Drug Control is responsible for drafting national sampling testing plans and programs, organizing, implementing and providing technical guidance according to the requirements of the NMPA, collecting, analyzing, and reporting the national sampling testing data, and organizing quality analysis and information sharing application.

Cosmetic testing institutions with corresponding testing qualifications shall undertake relevant testing tasks.

Standards for the Management of Cosmetic Sampling Testing

Article 5 General Work Requirements The department responsible for medical products supervision and administration shall follow the principles of fairness, impartiality, and openness, organize and carry out sampling testing, and strengthen the supervision and administration of sampling units, testing institutions and the sampling testing process in accordance with the law.

Article 6 Enterprise Obligations The cosmetics manufacturer and operator is the first person responsible for the safety of cosmetics, and shall cooperate with the sampling testing organized by the department responsible for medical products supervision and administration, and shall not interfere with or refuse the sampling testing, shall not transfer or hide the cosmetics, and shall not refuse to provide proof documents or provide false information.

The registrant and notifier of imported cosmetics shall designate an enterprise legal person within China's territory as the domestic responsible person to cooperate with the sampling testing of imported cosmetics.

The cosmetics e-commerce platform operator shall strengthen the management of the operators on the platform, assist and cooperate with the department responsible for medical products supervision and administration in the sampling testing and related checking and disposal work, and promptly stop sales for unqualified products after the sampling testing through measures of deleting, blocking, disconnecting, and terminating transactions and services.

Article 7 Information Management The NMPA shall establish a sampling testing information management system (hereinafter referred to as the sampling testing system) to regularly summarize and analyze the sampling testing data.

The department in charge of medical products supervision and administration, the institution undertaking sampling testing tasks, etc. shall submit the national sampling testing data and related information in the sampling testing system timely.

Article 8 Payment for Sampling testing For sampling testing, the cost of samples shall be paid. Expenses relating to sampling testing shall be included in the budget of the government at the same level.

Article 9 Separation of Sampling testing A scheme of separating sampling and testing shall be implemented for sampling testing. Except for on-site inspection, sampling personnel shall not undertake the testing of their samples.

Chapter II Plan

Article 10 Annual Plan The NMPA and the provincial medical products administration



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