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Interim Provisions on the Administration of Overseas Inspection of Cosmetics (Draft for Comments)

《化妆品境外检查暂行管理规定（征求意见稿）》

China National Medical Products Administration

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Interim Provisions on the Administration of Overseas Inspection of Cosmetics

(Draft for Comments)

Chapter 1 General Principles

Article 1 These Provisions are formulated to regulate the overseas inspection of cosmetics.

Article 2 These Provisions shall apply to the inspection of overseas development and production related processes of cosmetics that have been marketed or are to be marketed within the territory of the People's Republic of China.

Article 3 Overseas inspection of cosmetics refers to the overseas on-site inspection carried out by the National Medical Products Administration (hereinafter referred to as NMPA) to confirm the authenticity, reliability and compliance of the overseas development and production related processes of cosmetics and the application materials.

Article 4 NMPA is responsible for administration of the overseas inspection of cosmetics. The Center for Food and Drug Inspection of National Medical Products Administration (hereinafter referred to as the Center for Inspection) is responsible for the specific organization and implementation of overseas inspection of cosmetics; Relevant departments such as inspection, review and evaluation of cosmetics shall assist with overseas inspection.

Article 5 NMPA shall, in accordance with the requirements for disclosure of government information, disclose the basic information of the inspection and the handling results.

Article 6 Inspectors and inspected units shall strictly abide by relevant requirements for anti-corruption.

Article 7 Inspectors shall strictly abide by laws, regulations and inspection disciplines, and keep state secrets, work secrets and secrets of the inspected units.

Article 8 Registrants or filing persons shall fully coordinate and cooperate with overseas inspection work to ensure smooth inspection and must not delay, obstruct, evade or refuse inspection.

Chapter 2 Inspection Plan and Preparation

Article 9 At the end of last year, NMPA determines the annual inspection plan through risk assessment and random spot checks based on the suggestions of various relevant departments on the varieties to be inspected and relevant development and production sites. If it is really necessary to make changes to the inspection plan according to regulatory requirements, the inspection plan may be adjusted in accordance with relevant provisions of NMPA on foreign affairs administration of overseas inspection.

Article 10 The determination of the inspection plan shall be based on the principle of risk control and shall focus on the safety risk factors found in cosmetics registration and filing, inspection, test, adverse reaction monitoring, complaints and reporting, etc., including following circumstances:

(1) Potential risks are found in the review and approval process;

(2) The inspection results do not conform to the provisions, suggesting that there is a safety risk in the quality system;

(3) Adverse reaction monitoring suggests that there may be product safety risks;

(4) Complaints and reporting or other clues suggest the existence of illegal activities;

(5) The registrant or filing person has bad records or acts of dishonesty;

(6) The disclosure information of overseas regulatory agencies suggests that there is a greater risk in the quality management system or products of the registrant or filing person;

(7) Other circumstances needing to carry out overseas inspection.

Article 11 According to NMPA's overseas inspection plan, the Center for Inspection shall send the Notification of Overseas Inspection (Attachment 1) to the registrant, the filing person or their agents. The registrant or the filing person shall submit the agent authorization form (see Attachment 2 for relevant

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