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License Management Approach for Cosmetics Manufacturers

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Chapter 1. General Provisions

Article 1. This approach is set up in accordance with the People's Republic of China Administrative Licensing Law (hereinafter referred to as the Administrative Licensing Law), and Cosmetics Health Supervision and the relevant laws and regulations, to regulate the management of cosmetics manufacturers license.

Article 2. This approach applies to the review, approval, supervision and management of the cosmetics manufacturing enterprises within the People's Republic of China.

Article 3. The State Food and Drug Administration is in charge of the license management of the cosmetics manufacturing enterprise on the nationwide scale. The food and drug supervision and management departments of all provinces, autonomous regions, and municipalities (hereinafter referred to as provincial level food and drug supervision and management departments) are responsible for the cosmetics manufacturers license management within its administrative area. Food and drug supervision and administration departments above the county level are responsible for day-to-day supervision and management of the cosmetics manufacturers within its administrative area.

Article 4. Food and drug supervision and management departments while licensing the cosmetics manufacturers shall stick to the power limit, scope, conditions and procedures of China's laws, regulations and rules, and adhere to the principle of openness, fairness, justice, and convenience.

Article 5. All units and individuals who discover violation of this approach have the right to report to the food and drug supervision and management departments. Those departments in charge shall check and handle it in time.

Article 6. The State Food and Drug Administration and the provincial food and drug supervision and management departments should establish and improve the cosmetic manufacturers licensing information management system, timely publication of cosmetics manufacturers to license the relevant information.

Chapter 2. Application and Approval

Article 7. Companies applying for license of cosmetics manufacturing (hereinafter referred to companies) shall meet the following requirements:

(1) Employees shall be in good heath condition, well trained and familiar with the operating rules. Personnel in charge of on-site production and product safety shall also have to be familiar with relevant rules and regulations on cosmetics. Also required are the education level—college education and above, technical title—the intermediate level and above, at least 3 years of work experience or the quality and safety management experience in cosmetics; inspectors, however, shall have received education on cosmetics testing in secondary technical school and have obtained relevant qualification through professional training;

(2) Companies shall be in possession of suitable plant facilities, production and testing equipments to the type and scale of production. Also needed are reasonable production layout and proper process flow;

(3) Production site shall be clean, and far from toxic and harmful places and sources;

(4) Companies shall put in place a management system to ensure product quality;

(5) Companies shall meet the other requirements in Cosmetics Manufacturers Hygienic Practices.

Article 8. Application companies shall send application to the provincial level food and drug supervision and management departments of the production site and submit and the following materials:

(1) Application form for cosmetics manufacturers license;

(2) Printed copy of enterprise business license, or copy of the pre-approval notice issued by the Administrative Bureau for Commerce and Industry;

(3) Copy of identification of the enterprise legal representative (or owners of enterprise);

(4) Catalogue of the production and quality administrator and inspectors, including their names, education level, titles, and trainings they acquire;

(5) General plan sheet of the factory (including the environment and hygiene condition of 30 meter area around the outside of the factory), plan sheet of the production site (including the diagrams of the workshop, storage, testing room, sample room, as well as the diagrams of the personnel flow and logistics), and deployment diagrams of the equipments;

(6) Clear lists of the major production equipments and inspection equipments (equipment names and quantities included);

(7) Proposed product categories and major varieties;

(8) Brief introduction and process flow sheet of the proposed product categories and varieties;

(9) The copy of the production record and inspection report of one batch of major varieties;

(10) Content of the management files, including production management, product quality management, and personnel management files;

(11) Inspection reports. The following contents are usually included:

A. Quality report of water for industry use;

B. The total number of bacteria In the workshop;

C. Companies producing skin care cosmetics for eye use and for children and infant use shall have to provide an inspection report on a clean area setting of 300,000;

D. Report on the overall illumination of work shop and inspection room

The inspection report must be certified by China's recognized inspection body within a year.

(12) Other materials required by provincial level food and drug supervision and management departments. Application companies shall be responsible for the authenticity of the contents in the materials.

Article 9. Food and drug supervision and management departments shall conduct a thorough review over the completeness and format of the material within five working days as of the reception date of the materials

Article 10. Food and drug supervision and management departments shall pay special treatment to those application companies found of the following incidents according to actual situation:

(1) Ignore the application companies whose application items are in no need of license;

(2) Ignore the companies whose application items are beyond the administration range of the department. The application companies shall also be informed of the direct administrative departments;

(3) In the event that application materials have mistakes correctable on site, companies can apply for on-site correction, but technical contents are excluded and seals are needed for confirmation;

(4) In the event that application materials are incomplete or do not meet the statutory requirements, departments shall inform the application companies of the materials on the spot

or within five working days. Those who do not receive any notice shall be handled the day they submit the application form;

(5) In the event that application materials are still incomplete or do not meet the statutory requirements, food and drug supervision and management departments have the right to urge them for further correction. If there is no good reason, applicants are deemed in default if they are not able to submit corrected materials within two months since the correction date.

(6) In the event that the application items are complete and within the power limit of the departments, and that they meet the statutory requirements of China, application for license shall be handled after the corrected materials are turned in

Article 11. Food and drug supervision and management departments shall in time carry out technical review over the license application. At least two personnel shall be designated on the spot to exercise the review according to the hygiene practice of cosmetics manufacturers.

On-site review usually includes the following items:

(1) Company locations and sanitary conditions of the factory and areas around it;

(2) Layout of the production site, process flow, building materials and the decoration;

(3) Setting up of the sanitary facilities;

(4) The setting up of production equipment, testing equipment;

(5) Pilot run condition (relevant records included);

(6) Sanitary conditions of storage of raw materials, packaging materials, finished product (sample included);

(7) Product quality regulation and its implementation;

(8) Safety risk assessment of the substance likely to occur in production;

(9) Organizational structure and its personnel deployment;

(10) Results of the cosmetics regulations tests for production management personnel and product quality and safety management personnel;

(11) Qualification of inspectors; check-up results and training certificate of employees; Technical review shall have to be accomplished within 20 working days after the application is accepted.

Article 12. The food and drug supervision and management departments shall make decisions to grant administrative permission to those whoever are qualified within 20 working days since

the completion date of technical review; for those who had failed to meet specified requirements, the decision of disapproval must be explained in written form and the applicant shall be notified about the right to administrative reconsideration or administrative lawsuit. The food and drug supervision and management departments shall issue Hygiene License for Cosmetics Manufacturers within 10 working days after the approval decision is made.

Article 13. Applicants have the right to submit an application of withdraw before any administrative decision is made. The food and drug supervision and management departments shall terminate the technical review and return the application materials according to actual situation, with an exception that the submitted materials are suspicious of forgery.

Article 14. The municipal food and drug department may be allowed to conduct on-site inspection over application for cosmetic manufacturers license within its administrative area by the provincial level food and drug supervision and management departments.

On receiving an application, the municipal food and drug department must conduct an examination over the application materials and decide whether to accept the application or not within five working days. If accepted, opinions on inspection shall be proposed and submitted together with all the application materials to the provincial level food and drug supervision and management departments within twenty working days. Then the provincial level food and drug supervision and management departments shall make decisions over whether to grant the administrative permission to the enterprise in issue or not within 20 working days.

Those authorized municipal food and drug department that are responsible for handling application and on-site inspection must be made public by the provincial level food and drug supervision and management departments and recorded by SFDA.

Chapter 3. Alteration, Extension and Reissue

Article 15. Changes of items registered clearly on Hygiene License for Cosmetics Manufacturers including corporate name, registered address, legal representative (person in charge), or when production site undergoes textual alteration (actual production site does not change), the enterprise of cosmetics production must apply for alteration to the original issuing organ and fill out requested form of Alteration Registration Application while submitting relevant credentials issued by related organs.

If the application for alteration registration is approved, a new certificate of Hygiene License for Cosmetics Manufacturers would be issued. The certificate will preserve the original license number and term of validity but with a mark of “alteration” on it.

Article 16. Enterprise of cosmetics production shall reapply for Hygiene License for Cosmetics Manufacturers when changes occur in areas of production categories or production sites. Meanwhile the enterprise shall submit its current production categories, product variety and related certification or recorded registration forms. The Food and Drug Administration shall issue a new certificate of Hygiene License for Cosmetics Manufacturers to those that meet the prescribed conditions with the original license number unchanged.

When its production plant needs reconstruction or expansion, the enterprise of cosmetics production shall report to the original issuing organ for approval. The provisions of the preceding paragraph shall be still applicable when the basic production conditions change.

Article 17 The term of validity of Hygiene License for Cosmetics Manufacturers is four years.

If the enterprise of cosmetics production wishes to extend the term of validity when it comes to expiration, the enterprise shall apply to the original issuing organ for extension three months before the expiration date. The following materials shall be submitted:

(1) Form of Extension Application for the Hygiene License for Cosmetics Manufacturers;

(2) Production categories, production variety and related certification or recorded registration forms;

(3) Brief introduction into and process flow sheet of the main product variety;

(4) List of production management personnel, product quality and safety management personnel and inspectors, including their names, education levels, professional titles and training experiences;

(5) Other materials required by the Provincial level Food and Drug supervision and management departments.

For those that exceed the time limit for extension application, the enterprise may reapply for the Hygiene License for Cosmetics Manufacturers.

Article 18. The original issuing organ shall make the decision whether to grant the extension application or not based on conditions of enterprise compliance with related laws, regulations, rules and hygiene practices of cosmetics production. If the extension permission is granted, then the original certificate will be called back and a new one would be issued instead with the original license number unchanged.

For extending the certificate of Hygiene License for Cosmetics Manufacturers, the Food and Drug Administration shall conduct on-site inspection. Besides, the departments shall also examine production records, inspection records, reporting cargoes and other records.

Article 19. When loss of the Hygiene License for Cosmetics Manufacturers occurs, the enterprise of cosmetics production shall make a loss statement in any newspaper or magazine above the provincial level and apply for reissuing to the original issuing organ within sixty days since the loss. In the event that the Hygiene License for Cosmetics Manufacturers is damaged, companies can apply for reissue with the original damaged one as a proof.

Reissuing date of the Hygiene License for Cosmetics Manufacturers is the actual granting date. The original license number, validity term and other contents will not be changed, but with a “reissue” mark on it.

Chapter 4. Certificate Management

Article 20. The model and style of the Hygiene License for Cosmetics Manufacturers shall be stipulated by the Food and Drug Administration uniformly.

Article 21. The Hygiene License for Cosmetics Manufacturers shall contain the following contents: corporate name, legal representative (person in charge), registered address, production site, production categories, certificate license number, issuing organ, issuing date, valid term, remarks and other key information. The corporate name and the legal representative (person in charge) shall be in consistence with that approved by the Administrative Bureau for Commerce and Industry.

The format of Hygiene License for Cosmetics Manufacturers is as follows: Province, Autonomous regions, Abbreviation of municipality + Cosmetics Production Hygiene license number + Year (four Arabic numbers) + sequence number (four Arabic numbers).

Article 22. One cosmetics production site only allows applying for one certificate of Hygiene License for Cosmetics Manufacturers. Other cosmetics production sites of the same cosmetics enterprise shall apply for separate certificates of Hygiene License for Cosmetics Manufacturers accordingly.

Article 23. Cosmetics manufacturing establishments shall not be used for the production of other products that may affect the quality and safety of cosmetics.

Cosmetics manufacturing enterprises should organize production in accordance with the certificate of Hygiene License for Cosmetics Manufacturers in terms of production categories. Otherwise, those products that go beyond the prescribed production categories may be deemed as unlicensed products

Article 24. The certificate of Hygiene License for Cosmetics Manufacturers shall not be loaned, leased or transferred to others. Neither could it be forged or sold.

Article 25. The provincial level food and drug supervision and management departments have the right to revoke the certificate of Hygiene License for Cosmetics Manufacturers if one of the following cases occurred:

(1) The certificate of Hygiene License for Cosmetics Manufacturers expires, and the enterprise did not initiate an extension application or failed the extension application;

(2) The enterprise of cosmetics production is terminated in accordance with the law;

(3) Before the expiration is due, the enterprise applies for cancellation;

(4) The certificate of Hygiene License for Cosmetics Manufacturers is cancelled or revoked;

(5) Enterprise Business License was suspended or revoked by the Administrative Bureau for Commerce and Industry;

(6) Other circumstances that should be revoked.

Chapter 5. Sub-Contract Production

Article 26. If the cosmetics were commissioned to other party for production, then the entrusting party and entrusted party shall sign a contract in written form. The two parties shall report to the provincial level food and drug supervision and management departments where the production site of the entrusted party under supervision within thirty days after signing the contract.

Article 27. The entrusting party shall be responsible for the quality and safety of the products that are commissioned to be manufactured. The entrusted party shall meet the hygiene practices for cosmetics production and be responsible for the corresponding legal liability.

Article 28. The entrusting party must meet the following basic conditions:

(1) In possession of the certificate of Hygiene License for Cosmetics Manufacturers;

(2) Must have person in charge of product quality and safety of the commissioned products;

(3) Have quality and safety management system including production tracking, product inspection and receipt, product handover, product testing, delivery, sales, recycling, complaint dealing and others;

(4) Permit for the commissioned production or certificate of recording registration;

Article 29. The entrusted party must meet the following basic conditions:

(1) In possession of the certificate of Hygiene License for Cosmetics Manufacturers, and the prescribed production categories must be in accordance with the commissioned production categories;

(2) The production site, facilities, equipments and other conditions must meet requirements for product variety and gross amount in the same period.

Article 30. In case of commissioning cosmetics production, the following materials shall be submitted for record keeping:

(1) Recording form for commissioning cosmetics production;

(2) The commission contract between the entrusting party and the entrusted party;

(3) Copy of the Hygiene License for Cosmetics Manufacturers and enterprise business license of the both parties;

(4) Permit for the commissioned production or certificate of registration record; Brief introduction of commissioned product variety processing, flow chart and related standards for product quality and safety should also be submitted;

(5) Documents for product quality and safety management system of the entrusting party;

(6) The names of both the entrusting party and entrusted party, production address, the number of the Hygiene License for Cosmetics Manufacturers, and other relevant information in accordance with national regulations must be marked on the label and introduction (sample manuscript) of the commissioned products;

(7) Letter of Commitment to Product Quality and Safety from both the entrusting party and the entrusted party.

Article 31. When the commission contract terminates or recorded content changes, the entrusting party and entrusted party shall immediately report to the original provincial level food and drug supervision and management departments for approval.

Chapter 6. Supervision and Inspection

Article 32. The Provincial level Food and Drug supervision and management departments shall be responsible for hygiene supervision and inspection over those cosmetics enterprises within its own administrative area. The departments shall establish operation mechanism and management system for conducting supervision and inspection. The departments shall also clarify the specific responsibilities of supervision and inspection for municipal and county food and drug departments.

China's State Food and Drug Administration shall reserve the right to supervise and selectively examine over the license management and sanitation inspection work conducted by food and drug supervision and management departments at all levels. If necessary, the State Food and Drug Administration would initiate direct supervision and inspection over certain enterprise of cosmetics production.

Article 33. When food and drug supervision and management departments conduct hygiene supervision and inspection, it shall work out specific inspection program with clearly defined requirements and standards included. The department is required to accurately record the inspection results, which should be later sent to the enterprise in written form. The departments shall lay out the content and time limit for rectification to those enterprises in need of alteration, and follow-up inspection shall be conducted later.

When supervision and inspection is carried out, at least two inspectors shall be assigned. The inspectors shall produce legal documents to the enterprise under inspection and shall not leak out any confidential information of the enterprise.

Article 34. The Food and Drug Administration shall pay particular attention to the following cases for inspection:

(1) The Certificate of Hygiene License for Cosmetics Manufacturers, and its corresponding changes and reviews;

(2) The enterprise business organization, production management, personnel in charge of product quality and safety, and changes of production and inspection conditions;

(3) The operation of production process and management of product quality and safety;

(4) Cooperation with previous supervision and inspection practices and the implementation of rectification required by the departments;

Enterprises of cosmetics production shall cooperate with the Food and Drug Administration for conducting supervision and inspection and guarantee to provide authentic materials.

Article 35. When the supervision and inspection practices are undergoing, the Food and Drug Administration shall ensure that they will not impede the normal production activities of the cosmetics manufacturer. Neither could the administrative personnel ask for or accept the property or any other interests from the cosmetics manufacturer.

Article 36. The Food and Drug Administration and its personnel must conform to their duties of cosmetics production licensing, and consciously accept supervision from the cosmetics enterprises and the community.

Whenever the Food and Drug Administration receives reports concerning violations of this practice of cosmetics production licensing, it shall make prompt investigation and deal with it immediately.

Article 37. For those related staff that may violate this practice of cosmetics manufacturing licensing, food and drug supervision and management departments shall educate the relevant personnel, remove relevant staff and confer training on them, revoke their qualification and other appropriate punishments according to the seriousness of violation.

When investigating and affixing legal liability for violation of this practice, the following principles must be referred to:

(1) Inspector issues opinions favoring applicants that are certainly unqualified for manufacturing cosmetics, then this person must be held for responsible for this clear administrative violation;

(2) Inspector finds an applicant unqualified for cosmetics manufacturing licensing, but the person in charge still insists on issuing the certificate of Hygiene License for Cosmetics Manufacturers. Then accordingly this person in charge would be held responsible for this clear violation;

(3) If both the Inspector and person in charge violate this practice, then the person in charge shall be held responsible for this violation.

Article 38. If any one of the cases under Article Sixty-nine of the Administrative Licensing Law occurs, the China's State Food and Drug Administration or provincial level food and drug supervision and management departments shall revoke the certificate of Hygiene License for Cosmetics Manufacturers under the request of interested parties.

Chapter 7. Legal Liability

Article 39. If any applicant enterprise has tried to conceal relevant information or has submitted false materials to apply for the Hygiene License for Cosmetics Manufacturers, the Food and Drug departments has the right to refuse the application or disapprove the application. Meanwhile, a warning will be issued and the applicant enterprise cannot reapply for one year.

If obtainment of a certificate of Hygiene License for Cosmetics Manufacturers was based on bribery, cheating or any other inappropriate means, then the Food and Drug Administration shall revoke the certificate of Hygiene License for Cosmetics Manufacturers. Besides, the applicant enterprise cannot reapply for three years and a penalty fine within the range of RMB 10,000 and RMB 30,000 will be imposed.

Article 40. If any cosmetics enterprise that has been entrusted to manufacture cosmetics products for the entrusting party fails to record this commission in accordance with this practice, then a penalty fine within the range of RMB 10,000 and RMB 30,000 will be imposed by the Food and Drug Administration above the county level within its administrative area.

Article 41. If any one of the following circumstances occurs, a warning shall be imposed on the cosmetics enterprise by the Food and Drug Administration above the county level within its administrative area. Meanwhile the enterprise must make corrections within required time limit. If the enterprise fails to do so, it may pay a penalty fine within the range of RMB 10,000 and RMB 30,000:

(1) Fail to report to the provincial levelled food and drug supervision and management departments for rebuilding or expanding the manufacturing plant and continue to manufacture cosmetics;

(2) The site for manufacturing cosmetics is used for the production of other products that may affect the quality and safety of cosmetics;

(3) Mark the license number of Hygiene License for Cosmetics Manufacturers on other non-cosmetic products.

If any enterprise of cosmetics manufacturing proceeds to conduct unauthorized production when its basic production conditions have undergone changes because of expansion or reconstruction of the production site, then this enterprise will be punished according to the regulations of Article 24 of Cosmetics Hygiene Supervision and Inspection Regulations on basis of violation of licensing procedures for cosmetics manufacturers.

Article 42. If any enterprise of cosmetics manufacturing was found withholding information, submitting false materials, or refusing to turn in relevant materials while under supervision and inspection, the Food and Drug Administration beyond county level has the right to issue a warning and rectification order within required time limit in accordance with Cosmetics Hygiene Supervision and Inspection Regulations. The departments may suspend the enterprise's operation activities or revoke its certificate of Hygiene License for Cosmetics Manufacturers if circumstances were serious enough.

Chapter 8. Supplementary Articles

Article 43. Food and Drug supervision and management departments in provinces, autonomous regions and municipalities may reserve the right to formulate implementation rules in accordance with provisions of this practice and their specific local situations.

Article 44 This practice will come into effect from****(about three months after announcement). This practice will prevail over those previously issued provisions that may become inconsistent with it.

If any cosmetics enterprise has obtained its Hygiene License for Cosmetics Manufacturers before this practice comes into effect, then the license will still be valid before the prescribed expiration date.