Florida Rules 61N-1.010
Requirements for Manufacturing Cosmetics

(1) All persons who manufacture or relabel cosmetics in Florida must follow the minimum requirements for manufacturing contained in this section to help assure product safety and quality. If a person does not engage in all phases of cosmetic manufacturing, that person need only comply with paragraphs applicable to those operations in which the person is engaged.

(a) As used in this section, "good manufacturing practice" means that part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use. It is thus concerned with both manufacturing and quality control procedures.

(b) As used in this paragraph, "internal audit" means a systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these rules and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

(c) As used in this paragraph, "standard operating procedure" means instructions on how to perform tasks and descriptions of the approved or required procedures for accomplishing specific quality assurance objectives.

(2) Buildings and facilities requirements.

Buildings and facilities used for manufacture, processing, packaging, or relabeling of cosmetics must:

(a) Be constructed and maintained in a clean and orderly manner to prevent selection errors (i.e., mix-ups) or cross contamination between consumables, raw materials, intermediate formulations (i.e., in-process materials), and finished products (this applies to containers, closures, labels and labeling materials as well);

(b) Be free of filth and infestation by rodents, birds, insects, and other vermin;

(c) Have a designated quarantine area for the storage of products that are suspected of being contaminated, adulterated, or otherwise potentially injurious to users;

(d) Have floors, walls, and ceilings constructed of smooth, easily cleanable surfaces;

(e) Have adequate lighting and ventilation, and, if necessary for control purposes, screening, filtering, dust, humidity, temperature, and bacteriological controls;

(f) Have washing, cleaning, plumbing, toilet, and locker facilities to allow for:

1. Sanitary operation;

2. Cleaning of facilities, equipment and utensils; and,

3. Personal cleanliness; and,

(g) Have fixtures, ducts, pipes, and drainages installed to prevent condensate or drip contamination.

(3) Equipment requirements.

Equipment, machinery and utensils used in manufacturing, processing, packaging, or relabeling of cosmetics must be specifically designed and constructed for the intended purpose to prevent corrosion, accumulation of static material, and adulteration with lubricants, coolants, dirt, and sanitizing agents. The equipment must be:

(a) Maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants;

(b) Constructed to facilitate adjustment, cleaning, and maintenance;

(c) Constructed to ensure accurate measuring, mixing, and weighing operations;

(d) Calibrated regularly or checked according to a standard operating procedure with results documented; and,

(e) Removed from use if it is defective, does not meet recommended tolerances, or cannot be repaired and calibrated immediately.

(4) Personnel requirements.

(a) Personnel supervising or performing cosmetics manufacturing must have the education, training, experience, or combination thereof, to perform their assigned functions.

(b) Personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or contact surfaces must wear clean clothing appropriate for the duties they perform and necessary protective apparel (for example, uniforms, gloves, safety glasses, and hair restraints).

(c) Personnel must maintain adequate personal cleanliness, and be free from abnormal sources of microbiological contamination (for example, sores and infected wounds).

(d) Eating food, drinking beverages, or using tobacco must be restricted to designated areas away from storage and processing areas.

(e) All personnel and visitors must be supervised while in the manufacturing facility.

(f) Only authorized personnel shall be allowed access into production, storage, and product control areas.

(5) Raw materials requirements.

Raw materials must be identified, stored, examined, tested, inventoried, handled, and controlled. In particular, raw materials must be:

(a) Stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.);

(b) Held in closed containers and stored off the floor;

(c) Maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine);

(d) Sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage; and,

(e) Specifically identified and controlled to prevent the use of materials that would be injurious to users if such material were incorporated into a cosmetic product and such product were used under the conditions of use prescribed in the labeling or advertisement of the product or under such conditions as are customary or usual.

(6) Water requirements.

(a) There must be established procedures for ensuring that the water used as a cosmetic ingredient is being tested or monitored regularly.

(b) The entire system for supplying water used as a cosmetic ingredient must be set up to avoid stagnation and risks of contamination (this system shall be routinely cleaned and sanitized according to a standard operation procedure that ensures no biofilm build-up).

(7) Product requirements.

Cosmetic manufacturers shall develop and maintain written manufacturing and control standard operating procedures addressing formulations, processing instructions, in-process control methods, packaging instructions, and instructions for operating equipment; the procedures must include provisions to ensure that:

(a) The selection, weighing, and measuring of raw materials and the determination of finished yield are verified;

(b) Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification or designation, stage of processing and control status;

(c) There are measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material;

(d) There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing;

(e) The tamper-resistant packaging and labeling for liquid oral hygiene products and vaginal products meet the requirements of 21 CFR 700.25;

(f) The storage and handling of packaging materials that are intended to come into direct contact with the product prevent selection errors and microbiological or chemical contamination; and,

(g) Finished product packages bear permanent, unique lot or control numbers and there is a coding system that corresponds to these numbers.

(8) Laboratory controls.

Cosmetic manufacturers shall develop and maintain laboratory controls addressing sample collection techniques, product development specifications, test methods, laboratory equipment, and technician qualifications; the laboratory controls shall include provisions to ensure that:

(a) Raw materials (including water), in-process and finished product samples are tested or examined for identity and compliance with applicable specifications (for example, physical and chemical properties), microbial contamination, and hazards or other chemical contamination; and,

(b) Returned cosmetics are examined for deterioration, contamination, and compliance with the manufacturer's product development specifications.

(9) Internal audit requirements.

Cosmetic manufacturers must have internal audit procedures that ensure:

(a) Internal audits are conducted randomly and on demand for a specific reason;

(b) Internal audits are conducted by individuals who do not have direct responsibility for the matters being audited;

(c) All observations made during the internal audit are evaluated and shared with management, production, quality control, and lab personnel who are responsible for developing and implementing corrective measures; and,

(d) Internal audit follow-up confirms the completion or implementation of corrective actions.

(10) Complaints, adverse events and recall requirements.

Cosmetic manufacturers must have standard operating procedures sufficient to:

(a) Facilitate the receipt, processing, evaluation and follow up on written and oral complaints;

(b) Facilitate the identification and retrieval of reported adverse incidents involving allegations of bodily injury or harm;

(c) Facilitate the effective and efficient identification and recall of products, including market withdrawal; and,

(d) Ensure notification of adverse incidents and product recalls to state and federal regulatory agencies; such notification shall be no later than 30 calendar days of receipt of the adverse incident and no later than 10 calendar days where the manufacturer has declared a product recall.

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