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Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA–2018–N–2027 for "*Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Current Manufacturing Practices for the Cosmetics Industry*" (Publication Date: November 20, 2018)

Dear FDA Desk Officer:

The Natural Products Association (NPA) is submitting this letter as general comment to docket FDA–2018–N–2027 (Docket Name: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Current Manufacturing Practices for the Cosmetics Industry). The NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products, including conventional foods, medical foods, dietary supplements, and foods for special dietary use. The NPA is a non-profit 501(c)(6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. We are the oldest and largest trade association in the natural products industry representing over 1,100 members accounting for almost 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, homeopathic products, and personal care products (i.e. health/beauty aids, cosmetics). Many of our members manufacture,

distribute, or sell cosmetics, and NPA launched the NPA natural seal program for personal care products and
ingredients in 2008. Therefore, NPA has an interest to submit comments on this topic. Thank you for the opportunity to comment.

Background

On November 20, 2018, FDA announced a proposed collection of information submitted to the Office of Management and Budget to study the diversity of practices and standards employed across the cosmetic industry. FDA has chosen to conduct a voluntary survey, a one-time data collection, of cosmetics establishments to identify the current manufacturing practices used in the industry. The four areas under study are "*written procedures and documentation,*" "*buildings and equipment,*" "*materials and manufacturing,*" and "*quality control/product testing.*"

Legislative Efforts to Introduce Cosmetic GMPs

NPA is supportive of legislative efforts to elevate good manufacturing practices in the cosmetics industry. Most recently, Senator Orrin Hatch (R-UT) introduced S. 2003, the "*FDA Cosmetic Safety and Modernization Act,*" referred hereafter as the "*Hatch Bill.*" A bill in similar scope to bring personal care product reform legislation was the Personal Care Products Safety Act, introduced by Senators Dianne Feinstein (D-CA) and Susan Collins (R-Maine) on April 20, 2015 as Bill S.1014. Representative Pete Sessions (R-TX) also reintroduced a cosmetic modernization bill as H.R. 575 on January 13, 2017, which was a package of reforms first introduced in November 2015 as the Cosmetic Modernization Amendments of 2015 (H.R. 4075). While all three bills had mandatory GMP requirements as the main components, the Hatch Bill was the most reasonable. The Hatch Bill would have amended the Federal Food, Drug, and

Cosmetic Act by introducing measures to regulate ingredients, monitor adverse reactions to cosmetics, and establish good manufacturing practices.

The Hatch Bill contrasts with the Personal Care Products Safety Act in several ways. While both bills expand FDA's oversight abilities in the cosmetic and personal care space, the Hatch Bill relies on Congressional appropriations to fund the new work, whereas the Feinstein-Collins Bill would allow FDA to collect user fees from industry, providing for approximately $20 million from the largest cosmetic manufacturers. The Feinstein-Collins Bill places significant burdens on manufacturers to show that chemicals used in cosmetic products pose a "*reasonable certainty of no harm*" whereas the Hatch Bill places the burden on FDA to show a cosmetic chemical is "*not injurious*" under customary or usual use.

Why Require Cosmetic GMPs

There is a parallel between that can be drawn between the dietary supplement (DS) industry and cosmetic industry. Congress gave FDA the authority to develop good manufacturing practices with the Dietary Supplement Health and Education Act of 1994. While it took until 2007 for the industry to receive a final rule on supplements, NPA had created an industry-wide GMP certification standard by 1998. Many elements in this standard were used as the basis for FDA's proposed and final GMP rules for supplements. The DS GMPs have created a level playing field as it is no longer the large firms who are expected to have fully implemented GMPs. The medium sized firms have enjoyed greater levels of compliance and the smallest firms are being scrutinized. FDA is already looking noting GMP deficiencies during their inspections of firms. In one such inspection, an eye shadow product was found to be contaminated with an ocular pathogen *Bacillus cereus*. Currently, there is only a GMP guidance document at FDA, which serves as a regulatory tool for personal care product quality. This FDA guidance document is not legally binding, does not have the force of law, and does not mandate cosmetic inspections by federal investigators for compliance. A guidance document, in contrast to a federal law or Agency final rule, only represents the Agency's thinking on a particular subject. Only formal rulemaking

through public notice and comment would provide effective enforcement of GMPs in the cosmetics industry. Cosmetic GMPs, enforced by a final rule and an active inspection program, are a sign of a mature industry; therefore, our member cosmetic companies support cosmetic GMPs.

Other Considerations for Cosmetic Reform by FDA

However, in addition to mandatory GMPs, to be issued for the cosmetics industry in the form of final rulemaking and comment, facility registration, serious adverse event reporting (SAER), and a uniform labeling standard should be components as part of that overall cosmetic reform. This would provide a level playing field for the responsible cosmetics industry. What NPA does not want to see for the industry is user fees. Another aspect to consider in any regulatory change in cosmetics is a requirement for state pre-emption. If there is no state pre-emption, adoption of any new final federal rules on labeling, SAERs, GMPs, allowable limits on contaminants will result in a patchwork of rules to navigate from the states, starting with California. NPA believes the federal standard on cosmetic GMPs and labeling should for any federal standards adopted by the Agency should dictate one clear voice for the industry to follow. NPA would also like to see a federal definition for the term "*natura*l" on cosmetic products. NPA strongly believes that better clarity over use of the term "*natural*" on labels and in labeling will be a positive for the cosmetic industry. NPA developed a natural seal standard for personal care products and ingredients in 2008. NPA would be willing and interested to work with the Office of Cosmetics and Colors to help the Agency wrestle with how to define "*natural.*" NPA believes that our over 10 years of experience on defining "*natural*" for personal care products would be valuable to the Agency.

Cosmetic GMP Considerations

The cosmetics industry is not a one-size-fits-all industry. There is a wide variety of product types, diversity in manufacturing and distribution operations, differences in both the size and resources available to companies, within the cosmetic industry. NPA also recognizes that there are a variety of ways to meet individual requirements of GMPs and that different approaches and procedures may be most suitable and appropriate for individual companies. NPA believes the GMP dietary supplement final rule or even its proposed rule is an excellent starting point for the discussion. Cosmetics should not be treated as pharmaceuticals and cosmetic GMPs should not be treated as foods. They are somewhere in between. In order to address the diverse needs of the cosmetic industry and the need to develop a comprehensive set of GMP that are applicable, useful and suitable for all member companies, NPA has drafted a proposed list of GMP considerations for any cosmetic GMP standard. As such, a GMP rule addressing considerations in this document would allow the user considerable flexibility in how they meet the specified requirements.

The Company that holds the product label has ultimate responsibility for the assurance that a cosmetic product is manufactured according to GMP at all stages in the supply chain, from acquisition of raw materials through final product testing and distribution, but the contract manufacturer is also responsible. Any GMP program issued by FDA must deal with brand manufacturers, contract manufacturers, and own label distributors. Adherence to GMPs should also be a requirement of distributors, re-packers, and storage facilities.

NPA's Considerations for Cosmetic GMPs (Manufacturing, Holding, and Distribution of cosmetics)

1. Written Procedures for Personnel

1.1 Key Responsibilities

1.1.1 Management Responsibilities

1.1.2 Organization should be supported by the top management of the company.

1.1.3 Implementation of Good Manufacturing Practices should be the responsibility of the top management and should require the participation in all departments.

1.1.3.1 Management should define and communicate the area in which authorized personnel are allowed to access

1.2 Personnel Responsibilities

1.2.1 Understand their position in the organizational structure

1.2.2 Know their defined responsibilities and activities

1.2.3 Have access to and comply with documents relevant to their particular responsibility scope

1.2.4 Report irregularities or other non-conformities which may occur at their level of responsibilities

2. Written Procedures for Disease Control

2.1 Any person who has, by medical examination or supervisory observation, an illness or medical condition such as open lesions or infected wounds that could be a possible source of microbial contamination, **SHALL** be removed from the manufacturing process so as to prevent adulteration of the cosmetic product during manufacture and storage. Personnel **SHALL** be instructed to report such health conditions to their supervisors.

2.2 Written procedures **SHALL** be established and followed that define the standard requirements for these practices.

3. Written Procedures for Cleanliness

3.1 All personnel having direct contact with raw materials, in-process materials, exposed products, and packaging components, as well as those individuals utilizing processing equipment and utensils, **SHALL** conform to a level of basic hygiene and personal cleanliness to protect the product against adulteration. These methods may include, but are not limited to:

3.2 Wearing outer garments that protect against adulteration of product and equipment.

3.3 Maintaining personal cleanliness.

3.4 Washing hands thoroughly before starting work and at any other time when the hands may have become soiled or contaminated.

3.4.1 Removing all unsecured jewelry and hand jewelry, or covering hand jewelry that cannot be removed.

3.4.2 Using gloves that are maintained in an intact, clean and sanitary condition.

3.4.3 Wearing hair nets, caps, beard covers, arm covers, or other effective hair restraints.

3.4.4 Storing clothing or other personal effects outside of processing areas.

3.4.5 Excluding the consumption of food and drink, as well as the use of chewing gum and tobacco products.

3.5 Written procedures **SHALL** be established and followed that define the standard requirements for these practices.

4. Written Procedures for Education and Training

4.1 All personnel **SHALL** have written job descriptions and possess education, training and/or experience to perform their assigned function. All personnel **SHALL** receive GMP education and training to perform their assigned function.

4.2 Written records of education and training **SHALL** be retained and routinely updated in order to document education and training progress.

5. Supervision/Management Considerations

5.1 The responsibility for assuring compliance by all personnel to these requirements **SHALL** be assigned to qualified personnel with the proper education, training and/or experience.

5.2 Quality assurance/Quality control: Individual signing off on release of products into interstate commerce is responsible in cases where misbranded or adulterated (i.e. products with GMP issues are considered technically adulterated).

6. Plant and Grounds

6.1 *Grounds*

6.1.1 The grounds about a manufacturing plant SHALL be kept in a condition that will protect against the adulteration of the product. Methods include, but are not limited to:

6.1.1.1 Properly storing equipment and removing litter, refuse and vegetation within the immediate vicinity of buildings that could attract or harbor pests.

6.1.1.2 Maintaining roads, yards and parking lots, and draining areas that could contribute to product adulteration or harbor pests.

6.1.1.3 Disposal of all waste and rubbish so as to prevent adulteration of the cosmetic product during manufacture and storage, and to ensure a clean, safe work environment.

6.1.2 Written procedures **SHALL** be established and followed that define the standard requirements for these practices.

6.2 *Requirements for Plant Construction and Design*:

6.2.1 Plant buildings and structures **SHALL** be of a size, construction and design to facilitate maintenance, cleaning and sanitary operation, and to prevent mix-ups between different raw materials and products. The plant and facilities **SHALL**:

6.2.1.1 Provide sufficient space for the placement of equipment and the storage and segregation of materials.

6.2.1.2 Provide operating practices or effective design that reduces the potential for mix-ups or adulteration of in-process or finished products.

6.2.1.3 Facilitate maintenance functions including cleaning, sanitation, waste treatment and disposal, and the elimination and prevention of pest infestations.

6.2.1.4 Provide adequate lighting in manufacturing areas.

6.2.1.5 Provide safety-type light bulbs, fixtures, and skylights to protect product against possible adulteration by glass.

6.2.1.6 Provide ventilation, air filtration, heating and/or cooling to control microorganisms, dust, humidity, and temperature in order to prevent adulteration of cosmetic product, and provide a safe, clean work environment.

6.2.1.7 Provide screening or other protection against pests.

7. Sanitation of Buildings and Facilities

7.1 General Maintenance:

7.1.1 All buildings, structures, fixtures and equipment **SHALL** be constructed in such a manner that floors, walls, ceilings, work surfaces and equipment can be cleaned and sanitized. All buildings and fixtures **SHALL** be maintained in a sanitary condition and **SHALL** be kept in good repair.

7.1.2 Written records **SHALL** be maintained that document cleaning of process rooms and areas.

7.2 Requirements for Cleaning and Sanitizing Agents:

7.2.1 Cleaning and sanitizing agents, pesticide chemicals, and fungicides **SHALL** be safe and effective for their intended use.

7.2.2 Cleaning and sanitizing agents, pesticide chemicals, and fungicides **SHALL** be identified, used, held and stored in a manner that protects against adulteration of cosmetic raw materials, in-process or finished products, or contamination of processing equipment, utensils or packaging materials.

7.3 Requirements for Pest Control

7.3.1 Effective measures **SHALL** be taken to exclude pests from the processing areas and the entire Plant. The use of insecticides or rodenticides is permitted only under precautions and restrictions that protect against adulteration of raw materials, products, equipment or packaging materials.

7.3.2 Written records of pest control inspections **SHALL** be maintained.

7.4 Requirements for Water Supply:

7.4.1 Potable water, as a minimum quality water, at designated temperature and pressure, **SHALL** be provided in all areas where required for processing, cleaning, or for employee sanitary facilities. Water **SHALL** meet the standards prescribed in the EPA's Primary Drinking Water Regulations (40 CFR part 141).

7.4.2 Procedures **SHALL** be established and followed to assure that water used in processing operations meets microbial standards prescribed in the EPA's Primary Drinking Water Regulations (40 CFR part 141).

7.4.3 Written records shall be maintained to avoid stagnation and risks of contamination and follow sanitation procedures for equipment

7.5 Requirements for Plumbing:

7.5.1 Plumbing **SHALL** be of a size and design and installed and maintained to:

7.5.1.1 Carry sufficient quantities of water to required locations throughout the plant.

7.5.1.2 Properly convey sewage and liquid waste from the plant.

7.5.1.3 Avoid adulteration of product or contamination of water supplies or equipment.

7.5.1.4 Provide floor drainage in areas where floors are subject to flooding.

7.5.1.5 Prevent the contamination of fresh water with discharge wastewater or sewage.

7.6 Requirements for Sewage Disposal:

7.6.1 Sewage disposal **SHALL** be made into a sewage system.

7.6.1.1 Toilet Facilities:

7.6.1.1.1 Each Plant **SHALL** provide its employees with readily accessible toilet facilities.

7.6.1.1.2 Each Plant **SHALL** maintain the toilet facilities in a sanitary condition and in good repair at all times.

7.6.1.1.3 Each Plant should provide self-closing doors that do not open into areas where materials and/or product are exposed to airborne contamination.

7.6.1.2 Hand-washing Facilities:

7.6.1.2.1 Hand-washing facilities shall be convenient and furnished with running water and **SHALL** include:

7.6.1.2.1.1 Hand-washing facilities at each location where employees are required to wash their hands.

7.6.1.2.1.2 Effective hand-cleaning and sanitizing preparations.

7.6.1.2.1.3 Air dryers or sanitary towel services.

7.6.1.2.1.4 Devices or fixtures that protect against the recontamination of clean, sanitized hands.

7.6.1.2.1.5 Signs directing employees to wash hands before they start work, after each absence from their work station, or when their hands have become soiled or contaminated.

7.6.1.3 Rubbish Disposal:

7.6.1.3.1 Refuse receptacles and rubbish disposal practices that protect against adulteration or the harborage of pests **SHALL** be provided.

7.6.2 Supervision

7.6.2.1 The overall sanitation of the Plant **SHALL** be under the supervision of a qualified individual(s), with qualifications based on education, experience and/or training.

8. Equipment and Utensils

8.1 Requirements for Design and Construction:

8.1.1 Equipment **SHALL** be installed and maintained so as to facilitate the cleaning of the equipment and of the surrounding areas.

8.1.2 Equipment and utensils having direct contact with cosmetic raw materials, in-process materials, finished products **SHALL** be constructed of inert, non-toxic materials and designed to withstand the environment to which it is subjected during the manufacturing process and during cleaning.

8.1.3 Seams on utensils and processing equipment **SHALL** be smoothly bonded or maintained to minimize the accumulation of residues and the opportunity for growth of microorganisms.

8.1.4 All Plant equipment and utensils **SHALL** be so designed, constructed, and maintained as to preclude the adulteration of raw materials, packaging materials, in-process materials, and finished product with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

8.1.5 Cleaners, sanitizers, lubricants, and/or coolants used on utensils and processing equipment **SHALL** be suitable for use in cosmetic processing and manufacturing operations.

8.1.6 All equipment with critical parameters that require monitoring **SHALL** have suitable measuring devices such as time, temperature, weighing, pressure and/or speed controls, etc.

8.1.7 Each freezer and cold storage compartment **SHALL** be fitted with a temperature-measuring device, automatic control, or alarm system.

8.1.8 Compressed air and other gases that come into contact with a cosmetic product or cosmetic ingredient or used to clean equipment or utensils **SHALL** be treated in such a way that the materials they come in contact with are not adulterated.

8.1.9 Written procedures **SHALL** be established and followed that define the performance of routine preventative maintenance. Records **SHALL** be retained that document equipment maintenance.

8.1.10 Instruments and controls **SHALL** be accurate and maintained. Written records **SHALL** be retained that document maintenance and calibration of equipment.

8.1.11 Out of calibration equipment should be investigated to determine if there is any impact to the quality of the product and appropriate steps taken based on investigation.

8.2 Requirements and Written Procedures for Sanitation of Equipment and Utensils:

8.2.1 All utensils and equipment **SHALL** be cleaned, as frequently as necessary, using safe cleaning and sanitizing agents, and then stored in a manner that protects against recontamination.

8.2.2 Written procedures **SHALL** be established and followed for cleaning and maintaining equipment and utensils.

8.2.3 A written record of major equipment cleaning and use **SHALL** be maintained in individual equipment logs that show the date, product and lot number of each batch processed, and the cleaning and/or maintenance performed. The person(s) performing the cleaning and/or maintenance **SHALL** record in the log that the work was performed. Entries in the log should be in chronological order.

9. Quality Control and Laboratory Operations

9.1 Requirements and Written Procedures for Quality Control Operations

9.1.1 Quality control operations **SHALL** be employed to assure that cosmetic raw materials, in-process materials, finished cosmetic products conform to standards of purity, quality and composition, and that packaging materials are safe for their intended purpose.

9.2 Requirements and Written Procedures for Quality Control Unit and Change Control:

9.2.1 There **SHALL** be a quality control unit that has the responsibility and authority to:

9.2.1.1 Approve or reject all procedures, specifications, test methods and results that impact the purity, quality, and composition of an ingredient or product.

9.2.1.2 Approve or reject all raw materials, packaging materials, labeling and finished products, including contract-manufactured products, based upon conformance to established specifications.

9.2.1.3 Assure that completed production records are reviewed and **SHALL** have the final authority to determine if the product is approved for distribution. This evaluation **SHALL** be documented and maintained as part of the batch record.

9.2.1.4 Establish procedures for changing or revising all documentation (such as procedures, methods, record keeping, formulas, etc.).

9.2.1.5 Review and approve all changes to documentation (such as procedures, methods, record keeping, formulas, etc.).

9.2.1.6 Assure that the most current revision of all documentation (such as procedures, methods, record keeping, formulas, etc.) is in use at all times.

9.2.2 Written documentation for change control. How are raw materials reconditioned or re-used and the written criteria for defining when change control/deviations are accepted and when they are not? These responsibilities and authorities **SHALL** be established in writing and followed.

9.3 Requirements for In-house and/or Contract Laboratories:

9.3.1 In-house and/or contract laboratories **SHALL** be available for performance of the above tasks and responsibilities, and these responsibilities **SHALL** be established in writing and followed.

9.3.2 Test Methods:

9.3.2.1 All test methods **SHALL** be reliable and yield reproducible results.

9.3.3 Laboratory Records:

9.3.3.1 Laboratory records **SHALL** be maintained of data derived from all specified tests.

9.3.4 Shelf Life Labeling:

9.3.4.1 All products **SHALL** bear an expiration date or a statement of product shelf life. These dates **SHALL** be supported by data to assure that the product meets established specifications throughout the product shelf life.

9.3.4.2 Accelerated stability studies or data from similar product formulations may be used for an initial determination of shelf life. Product shelf life **SHALL** be confirmed and may be extended on the basis of real time studies on product stored under labeled storage conditions.

10. Production and Process Controls

10.1 Requirements and Written Procedures for Master Production and Control Records:

10.1.1 A master production and control record **SHALL** be prepared for the manufacture of each product and **SHALL** be reviewed and approved by the quality control unit.

10.1.2 Master production and control records **SHALL** include:

10.1.2.1 A complete list of raw materials used in the manufacture of the product, designated by names or codes sufficiently specific to indicate any special quality characteristic(s).

10.1.2.2 The amount of each raw material used. Each batch shall be formulated to provide not less than 100% of each claimed cosmetic ingredient.

10.1.2.3 The name and weight or measure of each cosmetic ingredient per unit or portion, or per unit of weight or measure of the product.

10.1.2.4 A statement concerning any calculated excess of cosmetic ingredient contained in the product.

10.1.2.5 A statement of the total weight or measure of any cosmetic supplement unit.

10.1.2.6 A statement of the theoretical weight or measure of the manufactured product and the acceptable range beyond which an investigation is required.

10.1.2.7 A description of the product container(s), closure(s), and finished product packaging labels, including positive identification of all labeling used.

10.1.2.8 Manufacturing and process control instructions.

10.2 Requirements and Written Procedures for Batch Production and Control Records:

10.2.1 Batch production and control records **SHALL** be prepared and followed for each batch of product. These records **SHALL** be an accurate representation of the master production and control record and **SHALL** include documentation that each significant step in the manufacturing process was accomplished, including:

10.2.1.1 Dates;

10.2.1.2 Identity of individual major equipment and lines used;

10.2.1.3 Specific identification, including lot number, of each raw material or in-process material used;

10.2.1.4 Weight or measure of each raw material used in the course of processing;

10.2.1.5 In-process testing results, if performed;

10.2.1.6 Quality control results;

10.2.1.7 Inspection of the packaging and labeling areas;

10.2.1.8 A statement of the actual yield at the conclusion of the manufacture and a statement of the percentage of theoretical yield, as appropriate;

10.2.1.9 Label control records, including specimens, copies or records of all labels used;

10.2.1.10 Description of product containers and closures used;

10.2.1.11 Description of any sampling performed;

10.2.1.12 Any special notes of investigations or deviations from the described process.

10.2.1.13 Identification of the persons performing and directly supervising described process.

10.2.2 Any deviations from written and approved specifications, standards and test methods **SHALL** be recorded on the batch record, and justified.

10.3 Requirements and Written Procedures for Handling and Storage of Raw Materials, In-process Materials and Rework:

10.3.1 Raw materials, in-process materials and rework **SHALL** be stored under conditions that will protect against adulteration and minimize deterioration.

10.3.2 Containers of raw materials **SHALL** be inspected upon receipt to assure that their condition has not contributed to the adulteration of deterioration of the contents.

10.3.3 Raw agricultural materials that contain soil, or other contaminants, **SHALL** be washed or cleaned, as necessary.

10.3.4 Raw materials, in-process materials, and rework **SHALL** be held in bulk, or in containers and under conditions of temperature and humidity that prevents the material from becoming adulterated or contaminated.

10.3.5 Written procedures **SHALL** be established and followed for the receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw materials.

10.3.6 Each lot of raw material **SHALL** be identified with a distinctive lot number and **SHALL** be controlled according to its status (e.g. quarantined, approved, or rejected).

10.3.7 Each lot of raw material, in-process material, and rework **SHALL** be examined or tested for filth, insect infestation, or other visually evident extraneous materials, microbial contamination, aflatoxin or other natural toxins, and all other established specifications, as necessary.

10.3.8 Each manufacturer **SHALL** have in place procedures to verify the identity of each lot of raw material.

10.3.9 Approved raw materials **SHALL** be rotated so the oldest approved stock is used first.

10.3.10 Raw materials **SHALL** be retested or reexamined after a specified time in storage or after exposure to conditions that are likely to adversely affect the purity, quality, or composition of the raw material.

10.3.11 Rejected raw materials **SHALL** be identified and controlled under a system that prevents their use in manufacturing or processing operations.

10.4 Requirements for Color Additives

10.4.1 Approved color additives are listed in 21 CFR parts 73,74, and 82.

10.4.1.1 Shall an ingredient be used as a color additive but not listed, approval of the petition of the new color additive is required pursuant to 21 CFR parts 70 and 71.

10.4.2 Color additives subject to certification must be labeled with the lot number assigned by the Color Certification branch (21 CFR 70.25 (d))

10.4.2.1 Except when any mixture for household use which contain not more than fifteen percent of pure color and in packages with less than 3 ounces appears on the label in which a code number will be placed in lieu of the lot number

10.5 Requirements and Written Procedures for Manufacturing Operations

10.5.1 All Inspection, manufacturing, packaging and storage operations **SHALL** be conducted in accordance with sanitation principles, in a manner that protects against adulteration and under conditions that minimize the potential for the growth of microorganisms.

10.5.2 Written procedures **SHALL** be established and followed for all inspections, manufacturing, packaging and storage operations.

10.5.3 Effective measures **SHALL** be taken to segregate raw materials, packaging materials, in-process materials, rework and finished products.

10.5.4 All containers, processing lines and major equipment used during the products of a batch **SHALL** be identified at all time to indicate their contents.

10.5.5 Effective measure **SHALL** be taken to protect against the inclusion of metal or other extraneous material in the product, including the use of sieves, traps, magnets and metal detectors.

10.5.6 Effective measure **SHALL** be taken for the identification, storage, and disposal of rejected or adulterated products.

10.5.7 Written procedures **SHALL** be established and followed that described tests to be conducted to assure the purity, composition and quality of the finished product.

10.5.8 Written procedures **SHALL** be established and followed for reprocessing batches that do not confirm to finished goods standards or specifications.

10.6 Requirements and Written Procedures for Packaging and Labeling Operations:

10.6.1 Filling, assembling, packaging and other operations **SHALL** be performed in such a way that products are protected against adulteration.

10.6.2 Written procedures **SHALL** be established and followed for the receipt, storage and examination of packaging materials.

10.6.3 Labels for each different product type, strength, or quantity of contents **SHALL** be stored separately.

10.6.4 Obsolete labels, labeling and other packaging materials **SHALL** be destroyed and such destruction documented

10.6.5 Written procedures **SHALL** be established and followed to assure that the correct labels and packaging materials are issued and used.

10.6.6 Packages **SHALL** be identified with a lot number that permits determination of the history of the manufacture and control of the batch.

10.6.7 Packaging SHALL be examined to provide assurance that containers and packages in the lot have the correct label and lot number.

10.6.8 Tamper-resistant packaging and labeling of liquid oral hygiene products and vaginal products must meet the requirements of 21 CFR 700.25

10.7 Requirements for Warehousing, Distribution and Post-Distribution Procedures

10.7.1 Storage and Distribution

10.7.1.1 Storage and transportation of finished product **SHALL** be conducted under conditions that protect against physical, chemical, and microbial adulteration, as well as deterioration of the products and the container.

10.7.1.2 Distribution records **SHALL** be maintained and retained by the manufacturer for at least 1 year beyond the expiration of shelf life date, whereby an effective product recall can be achieved.

10.7.2 Reserve Samples:

10.7.2.1 A reserve sample of each batch of a product **SHALL** be retained and stored under conditions consistent with the product labeling until at least 1 year after the expiration or shelf life date.

10.7.2.2 The reserve sample should be stored in the same container/closure system in which the finished product is marketed and **SHALL** be at least twice the quantity necessary to perform all the required tests.

10.7.3 Records Retention:

10.7.3.1 Any laboratory, production, control or distribution record **SHALL** be retained for at least 1 year after the expiration or shelf life date of the batch.

10.7.3.2 Raw material records **SHALL** be maintained for at least 2 year after the expiration or shelf life date of the last batch of product incorporating the raw material.

10.7.4 Written Recall Procedures:

10.7.4.1 Written procedures **SHALL** be established and followed that define the recall of a cosmetic product should said event become necessary.

10.7.5 Complaint Files

10.7.5.1 Written procedures **SHALL** be established and followed for the handling of all written and oral product complaints. Such procedures **SHALL** provide for review by the quality control unit and determination of the need for an investigation.

10.7.5.2 A written record of each complaint **SHALL** be maintained until at least one year after the expiration or shelf life date of the product, or one year after the date that the complaint was received, whichever is longer. The written record **SHALL** include, where known, name and description of the product, lot number, source and nature of the complaint, and response, if any. Where an investigation is conducted, the written record **SHALL** include findings of the investigation and follow-up action taken.

10.7.5.3 Complaints with adverse events involving bodily injury must include:

10.7.5.3.1 Description and severity of reported event

10.7.5.3.2 Body part involved

10.7.5.3.3 Whether medical treatment was sought and if so, nature of the medical treatment, name of physician or other health care professional

10.7.5.3.4 Whether resolution of the event occurred, short-term or long-term and if longer term nature of the effects.

10.7.5.3.4.1 If and whom the occurred event was reported to poison control, government agency

10.7.5.3.4.2 Whether the adverse event was voluntarily reported to the FDA through MedWatch program.

10.7.6 Returned Products:

10.7.6.1 Returned products **SHALL** be identified as such and held in a designated quarantined area.

10.7.6.2 The returned product **SHALL** be destroyed unless examination, testing, or other investigations prove the product meets standards of purity, composition and quality.

10.7.6.3 A returned product may be reprocessed provided that the subsequent product meets specifications.

10.7.6.4 Records pertaining to returned, reprocessed and redistributed products **SHALL** be maintained and **SHALL** include the name and description of the products, lot number, reason for return, quantity returned, date of disposition and ultimate disposition of the returned product

10.7.7 Product Salvaging:

10.7.7.1 Products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures **SHALL** not be salvaged and returned to the marketplace.

10.7.8 Voluntary Product Recalls

10.7.8.1 Written procedures **SHALL** be established and followed to assure that the proper procedures are in place and followed for conducting a recall

10.7.9 Defect Action Levels:

10.7.9.1 Some cosmetic ingredients and finished cosmetic products, even when produced under GMP, contain natural or unavoidable defects that at low levels are not hazardous to health

10.7.9.2 Defect action levels may also be established for cosmetic products whenever it is necessary and feasible to do so. The manufacturer of a cosmetic product **SHALL** at all times utilize quality control operations that reduce natural or unavoidable defects to the lower level currently feasible.

10.7.9.3 The mixing of a cosmetic ingredient containing defects above any established defect action level with another lot of cosmetic ingredient is not permitted and renders the final lot adulterated within the meaning of the act, regardless of the defect level of the final product.

11. Documentation

11.1.1 General Requirements for Written and Electronic Documentation and Systems Managements

11.1.1.1 Each company should establish, design, install and maintain its own system of documentation that is appropriate to its organization structure and to the type of products. An electronic system can be used to prepare and mange documents

11.1.1.2 Documentation is to describe activities defined in these guidelines in order to relate the history of activities and to prevent risks of interpretation, loss of information, confusion or errors inherent to verbal communication.

11.1.2 Type of Document

11.1.2.1 Documents should be composed of constituents such as procedures, instructions, specifications, protocols, reports,

methods and records appropriate to the activities covered by these guidelines.

11.1.2.2 Documents can be hard-copy papers or electronic records

11.1.3 Writing, Approval and Distribution

11.1.3.1 Documents should be defined and describe the operations to be carried out, precautions to be taken and measure to be applied in all activities connected with these guidelines.

11.1.3.2 Title nature and purpose of documents shall be stated

11.1.3.2.1 Documents should be:

11.1.3.2.1.1 Written in legible and comprehensive way

11.1.3.2.1.2 Approved, signed and dated by authorized persons before being used

11.1.3.2.1.3 Prepared, updated, withdrawn, distributed, classified

11.1.3.2.1.4 Referenced to ensure that obsolete documents are not used

11.1.3.2.1.5 Accessible to appropriate personnel

11.1.3.2.1.6 Removed from the job area and destroyed if they are outdated

11.1.3.3 Records which require the entry handwritten data should:

11.1.3.3.1 Indicate what is to be entered

11.1.3.3.2 Be written legibly with permanent ink

11.1.3.3.3 Be signed and dated

11.1.3.3.4 Be corrected, if needed, leaving the original entry still readable; where appropriate, the reason for the correction should be recorded.

11.1.3.4 Revision

11.1.3.4.1.1 Documents should be updated, when necessary and the revision number indicated. The reason for the revision should be retained.

11.1.3.5 Archiving

11.1.3.5.1.1 Only original documents should be archived and only controlled copies should be used.

11.1.3.5.1.2 The duration of the archiving original documents should be defined according to applicable legislation and regulations.

11.1.3.5.1.3 The storage of original documents should be properly secured

11.1.3.5.1.4 Documents may be archived as either electronic or hard-copies and their legibility should be ensured

11.1.3.5.1.5 Backup data should be stored at a separate and secure location at regular intervals.

Conclusion

It is our hope that FDA would use the Advanced Notice of Public Rulemaking (ANPR) process in any future attempts for cosmetic reform. The NPA thanks FDA for this opportunity to comment, and we look forward to participating in this important regulatory process of public notice and comment in the future with any ANPR announcement for any upcoming proposed rules on cosmetics GMP, cosmetic labeling, and cosmetic SAERs. NPA would like to engage FDA's Office of Cosmetics and Colors and assist them in the drafting of any proposed rules related to cosmetic reform, if that is the plan of the Agency. NPA hopes the FDA takes our cosmetic GMP suggestions for consideration.

Respectfully submitted,

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