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Guidance for Industry

Cosmetic Good Manufacturing Practices

Draft Guidance

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You may submit written comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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Table of Contents

I. Introduction

II. Background

III. Discussion

A. Overview

B. Definitions

C. Specific Guidance for Cosmetics

- **Documentation**
- **Records**
- **Buildings and Facilities**
- **Equipment**
- **Personnel**
- **Raw Materials**
 - Water*
 - Color Additives*
 - Prohibited and Restricted Cosmetic Ingredients*
- **Production**
- **Laboratory Controls**
- **Internal Audit**
- **Complaints, Adverse Events, and Recalls**

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Cosmetic Good Manufacturing Practices

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This document provides guidance to industry and other stakeholders (e.g., consumer interest groups, academia, other regulatory groups) on FDA's current thinking concerning what constitutes Good Manufacturing Practices (GMPs) for cosmetics. It is intended to assist industry and other stakeholders in identifying the standards and issues that can affect the quality of cosmetic products.

This guidance revises the "Cosmetic Good Manufacturing (GMP) Guidelines/Inspection Checklist" by updating it to set forth current practice, and clarify certain topic areas based on recent experience. In addition, as part of an international harmonization effort with the International Cooperation on Cosmetic Regulations (ICCR), FDA (or we) agreed to consider the current International Organization for Standardization (ISO) standard for cosmetic GMPs (ISO 22716:2007) when revising this guidance. We reviewed ISO 22716 and decided to incorporate, modify, or exclude specific aspects of it into this guidance based on our experience.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

The predecessor to this guidance, FDA's "Cosmetic Good Manufacturing Guidelines/Inspection Checklist," was based on documents and information dating before the early 1990's. Much of the material in the predecessor document has become outdated. In addition, there has been a great deal of progress in developing international consensus standards for cosmetics, specifically

¹ This guidance has been prepared by the Office of Cosmetics and Colors in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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Draft-Not for Implementation

ISO 22716 (*Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices*. ISO 22716:2007. Geneva, Switzerland:ISO.).

ISO is a non-governmental organization that develops and publishes international consensus standards. In September 2007, the International Cooperation on Cosmetic Regulation (ICCR), the quadrilateral international harmonization group, met in Belgium. During that meeting, the regulators from the United States, Canada, the European Union, and Japan agreed that it would be useful for the cosmetic industry to have a standardized scheme for GMPs that could apply to their jurisdictions. As a result, the regulators from these four jurisdictions agreed to take ISO standards for cosmetic GMPs into consideration when developing or updating guidelines or other measures addressing GMPs (See International Cooperation on Cosmetic Regulation: Outcome of Meeting, September 26-28, 2007). In developing this guidance, FDA has incorporated elements of ISO 22716, as appropriate, and consistent with FDA regulations.

III. Discussion

A. Overview

The Federal Food, Drug and Cosmetic Act (the FD&C Act) prohibits the introduction, or delivery for introduction, into interstate commerce of cosmetics that are adulterated or misbranded (Section 301 of the FD&C Act).

If you manufacture cosmetics, you can reduce the risk of adulterating or misbranding cosmetics by following the GMP recommendations in this guidance. By following these recommendations, you can effectively conduct a self-inspection to rate your operations.

Tampering and other malicious, criminal, or terrorist activity present additional risks that can also have a direct impact on your products' quality. To help minimize these risks to cosmetics under your control, we recommend that you consult a separate FDA guidance document entitled "Guidance for Industry: Cosmetic Processors and Transporters of Cosmetics Security Preventive Measures Guidance."

B. Definitions

We recommend that you refer to the FD&C Act and Title 21 of the Code of Federal Regulations (21 CFR) for definitions of the terms "cosmetic" (Section 201(i) of the FD&C Act) and "tamper-resistant packaging" (21 CFR 700.25). In addition, the following terms apply to this guidance:

Documentation: 1) The supplying of documents or supporting references; use of documentary evidence; 2) the documents or references thus supplied; 3) the collecting, abstracting, and coding of printed or written information for future reference. ("documentation," Webster's New World Dictionary Third College Edition, 1988 ed.).

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Good manufacturing practice (GMP): 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. (Sharp, John, Good Manufacturing Practice, Philosophy and Applications, Buffalo Grove, IL: Interpharm Press, 1991, pg. 47.).

Internal Audit: Systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these guidelines and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives. (*Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices*, ISO 22716:2007, Geneva, Switzerland: ISO.).

Standard operating procedure (SOP): Instructions on how to perform tasks and descriptions of the approved or required procedures for accomplishing specific quality assurance objectives. (Garfield, F.M., Klesta, E., and Hirsch, J., eds., Quality Assurance Principles for Analytical Laboratories, 3rd Ed., Gaithersburg, MD: AOAC International, 2000, pg. 26).

C. Specific Guidance for Cosmetics²

Documentation

Documentation creates a mechanism that shows how products are manufactured and tested. Documentation should define your organization's processes and capture every aspect of your manufacturing process. Documentation prevents errors of interpretation or loss of information that may result from reliance on verbal communication. Documentation also allows you to trace where any problems may have occurred and to take appropriate corrective action.

Records

Records should be retained in either paper or electronic format. Records should capture in detail the operations, procedures, deviations from procedures, justifications, instructions (including training), specifications, protocols, reports, methods, precautions, corrections and other measures, and other appropriate information related to GMPs.

You should review raw material records to determine if raw material is adequately controlled. These records may include origin, receipt, examination, testing, disposition, and use records.

You should determine whether disposition of rejected materials or returned goods is documented. (For example, reworking operations, returns to suppliers, and disposals).

You should evaluate batch production control records, which should include:

² There are no GMP regulations for cosmetics.

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- Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch
- Documentation of all production steps (for example, processing, handling, transferring, holding, and filling)
- In-process sampling, controlling, and adjusting steps
- Batch and finished product lot or control numbers
- The finished products control status – accepted or rejected

You should evaluate laboratory control records for raw materials, in-process materials, and finished products. These records should include documentation of sampling procedures, test results, and interpretation of the test results (accepts or reject).

You should determine if records are adequate to conduct an effective recall. Initial distribution records identifying the consignee, the product, and the lot or control number should be retained.

You should determine if records are developed in a timely manner after an event occurs.

Buildings and Facilities

You should determine whether the buildings and facilities used for manufacturing are of suitable size, design, and construction, and maintained in a clean and orderly manner. Buildings should provide:

- Space of sufficient size and adequate organization 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.)
- Adequate filth and pest controls (Examples of filth may include any objectionable matter, contributed by animal contamination such as rodent, insect, or bird matter; or any other objectionable matter contributed by insanitary conditions.)
- Floors, walls, and ceilings constructed of smooth, easily cleanable surfaces
- Adequate lighting and ventilation, and, if necessary for control purposes, screening, filtering, dust, humidity, temperature, and bacteriological controls
- Adequate washing, cleaning, plumbing, toilet, and locker facilities to allow for sanitary operation; cleaning of facilities, equipment, and utensils; and personal cleanliness; and
- Fixtures, ducts, pipes, and drainages installed to prevent condensate or drip contamination

Equipment

You should determine whether equipment and utensils used in processing, holding, transferring and packaging are of appropriate design, size, material and workmanship for the intended purpose to prevent corrosion, accumulation of static material and/or adulteration with lubricants, coolants, dirt, and sanitizing agents. The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be:

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Draft-Not for Implementation

- Maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants
- Constructed to facilitate adjustment, cleaning, and maintenance
- Of suitable size and accuracy for measuring, mixing, and weighing operations
- Calibrated regularly or checked according to an SOP with results documented, where appropriate
- Removed from use if it is defective, does not meet recommended tolerances, or cannot be repaired and calibrated immediately

Personnel

You should determine whether personnel supervising or performing cosmetics manufacturing or control have the education, training, and/or experience to perform their assigned functions. In addition:

- Personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or contact surfaces should wear clean clothing appropriate for the duties they perform and necessary protective apparel (for example, uniforms, gloves, safety glasses, and hair restraints).
- Personnel should also maintain adequate personnel cleanliness, and be free from abnormal sources of microbiological contamination (for example, sores and infected wounds)
- Eating food, drinking beverages, or using tobacco should be restricted to appropriate designated areas away from storage and processing areas
- All personnel and visitors should be properly supervised while in the manufacturing facility; and
- Only authorized personnel should be allowed access into production, storage, and product control areas

Raw Materials

You should determine whether raw materials are identified, stored, examined, tested, inventoried, handled, and controlled to ensure they conform to appropriate standards and specifications. In particular, raw materials should be:

- 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.)
- Held in closed containers and stored off the floor
- Maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine)
- Sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage (Animal and vegetable origin materials and those produced by cold processing methods should be reviewed for filth and/or microorganism contamination.); and
- Properly identified and controlled to prevent the use of materials that fail to meet acceptance specifications

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Water

You should determine whether:

- The water used as a cosmetic ingredient is used as-is (i.e., directly from the tap) or if it has been treated before being used (i.e., has it been treated by such means as deionization, distillation, or reverse osmosis)
- There are established procedures for ensuring that the water used as a cosmetic ingredient
 - Is of a defined quality
 - Is not affected by materials used in the water treatment equipment
 - Is being tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality; and
 - The entire system for supplying water used as a cosmetic ingredient is set up to avoid stagnation and risks of contamination (This system should be routinely cleaned and sanitized according to an appropriate SOP that ensures no biofilm build-up.)

Color Additives

You should determine whether color additives are approved for use in your specific cosmetic products (21 CFR parts 73, 74, and 82). Should an unlisted color additive be an ingredient of the cosmetic, approval of a petition for a new color additive is required pursuant to 21 CFR parts 70 and 71. A summary chart for color additives can be found on FDA's website. Color additives subject to certification must be labeled with the lot number assigned by the Color Certification Branch³ (21 CFR 70.25(d)) (see exception below⁴).

Prohibited and Restricted Cosmetic Ingredients

Certain ingredients are prohibited from use in cosmetic products marketed in the United States; others have restrictions on their use. Ingredients whose use is prohibited or restricted are listed in the tables below.

In addition to the prohibited and restricted ingredients listed in the following tables, you should check the CFR, specifically 21 CFR part 700, Subpart B, for any additional requirements regarding specific cosmetic products or their ingredients that may have been added to FDA's regulations.

³ The Color Certification Branch is located in the Office of Cosmetics and Colors in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

⁴ Color additives must be labeled with the lot number assigned by the Color Certification Branch, except in the case of any mixture for household use which contains not more than 15 percent of pure color and which is in packages containing not more than 3 ounces there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the FDA written notice that such code number will be used in lieu of the lot number (21 CFR 70.25(d)).

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Draft-Not for Implementation

Prohibited Cosmetic Ingredients	CFR Citation
Bithional	21 CFR 700.11
Vinyl chloride	21 CFR 700.14
Certain halogenated salicylanilides	21 CFR 700.15
Zirconium in aerosol products	21 CFR 700.16
Chloroform	21 CFR 700.18
Methylene chloride	21 CFR 700.19
Chlorofluorocarbon propellants	21 CFR 700.23
Prohibited cattle material	21 CFR 700.27

Restricted Cosmetic Ingredients	CFR Citation
Mercury compounds	21 CFR 700.13
Hexachlorophene	21 CFR 250.250

Production

You should determine whether written manufacturing and control SOPs have been established (for example, formulations, processing instructions, in-process control methods, packaging instructions, instructions for operating equipment). Procedures should include provisions to ensure that:

- The selection, weighing, and measuring of raw materials and the determination of finished yield are reviewed by a second individual
- Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification/designation, stage of processing and control status
- There are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material
- 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.
- The theoretical yield for a production batch is compared with the actual yield
- The tamper-resistant packaging and labeling for liquid oral hygiene products and vaginal products meet the requirements of 21 CFR 700.25
- 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
- Finished product packages bear permanent meaningful, unique lot or control numbers and you have a coding system that corresponds to these numbers

Laboratory Controls

You should evaluate laboratory controls including sample collection techniques, specifications, test methods, laboratory equipment, and technician qualifications. Laboratory controls should include provisions to ensure that:

- Raw materials (including water), in-process and finished product samples are tested or examined for identity and compliance with applicable specifications (for example,

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- physical and chemical properties), microbial contamination, and hazards or other chemical contamination
- Samples are representative of the lot
 - Current finished product samples as well as retained product samples are tested for adequacy of preservation against microbial contamination under reasonable conditions of storage and use
 - Samples of approved lots of raw materials and finished products are retained for an adequate time period
 - Retained samples are stored under conditions which protect their integrity (for example, to avoid contamination and deterioration), and are retested at appropriate intervals to assure continued compliance with established specifications; and
 - Returned cosmetics are examined for deterioration, contamination, and compliance with acceptance specifications

Internal Audit

You should determine whether effective procedures for internal audits are followed. At a minimum, internal audit procedures should provide that:

- Internal audits occur regularly or on demand
- Internal audits are conducted by individuals who do not have direct responsibility for the matters being audited
- All observations made during the internal audit are evaluated and shared with appropriate management, production, quality control, and/or lab personnel; and
- Internal audit follow-up confirms the satisfactory completion or implementation of corrective actions

Complaints, Adverse Events, and Recalls

You should review product complaints, consumer adverse event reports, and product recall files and determine the following:

- For complaints:
 - Whether there are SOPs for reporting, recording, filing, evaluating, and following up on both written and oral complaints
- For complaints alleging adverse events involving bodily injury:
 - The kind and severity of each reported injury
 - The body part involved
 - Product and code numbers
 - Whether medical treatment was sought, and, if so, the nature of the medical treatment and the name of the attending physician or other healthcare professional
 - Whether resolution of the event occurred, with or without long-term or persistent effects (If long-term or persistent effects occurred, the nature of those effects)

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- The name(s) and location(s) of any poison control center, government agency, physicians group, etc., to whom formula information and/or toxicity data has been provided; and
- Whether you are voluntarily reporting adverse events to FDA through the MedWatch program
- For voluntary product recalls, the guidelines in 21 CFR part 7, Subpart C, should be considered, including:
 - Whether there is a proposed strategy for conducting a recall
 - Whether recall notifications are capable of being initiated promptly
 - Whether the appropriate FDA district office has been notified of recalls
 - Whether recalled products have been identified and stored separately in a secure area until the firm has made a decision about the proper disposition or correction consistent with the degree of risk of the recalled product; and
 - Whether FDA's guidance as outlined in 21 CFR 7.59 has been considered