Supplier Requirements for Cosmetics, Beauty, & Personal Care Products

Health & Wellness Safety

Purpose

The requirements described in this document apply to anyone that supplies cosmetic products, as well as any agents they use (collectively, “Suppliers”), to be sold in Walmart stores and on Walmart.com by Walmart, Inc. (“Walmart”) and in Sam’s Clubs and on Samsclub.com by Sam’s West, Inc. (“Sam’s Club”). This document sets out the expectations and requirements for suppliers of non-prescription cosmetics beauty, and personal care products (“Cosmetic Products”). These products may be sold as National Brands, Private Brands, or via Direct Ship Vendors, as later defined. All products sold by Walmart and Sam’s Club must comply with all applicable laws and regulations, but this policy describes laws and regulations specific to the U.S. Food and Drug Administration (“FDA”) and other regulatory agencies that apply to cosmetics.

Walmart and Sam’s Club do not provide legal advice to Suppliers. Suppliers are responsible for compliance with this document and all federal, state, and local regulatory requirements throughout their operations and throughout the entire product supply chain. Suppliers must seek their own legal counsel to ensure compliance with all legal requirements applicable to their Cosmetic, Beauty, or Personal Care Product. A signed supplier agreement, acceptance of a purchase order, and/or provision of merchandise to Walmart or Sam’s Club constitutes acceptance and acknowledgement of these supplier requirements and serves as the Supplier’s continuing affirmation of compliance. Walmart reserves the right to audit or inspect Suppliers’ books and records, and any facilities they use, at any time. This document is incorporated by reference into the Walmart Supplier Agreement Standard Terms and Conditions (“Supplier Agreement”) and is in addition to the Responsible Sourcing Standards for Suppliers.

Failure to comply with all federal, state, and local regulatory requirements as described in this document and otherwise applicable to a Cosmetic Product supplied to Walmart or Sam’s Club violates the terms of the Supplier Agreement. This could result in removal from Walmart or Sam’s Club stores or omnichannel sales.

If you are unsure if the Cosmetic Products supplied to Walmart or Sam’s Club are subject to these requirements, please contact Health & Wellness Product Safety at HWSCSAFETY@wal-mart.com.

Cosmetic Product Supplier Types

Private Brand Suppliers:

Private Brand suppliers are those suppliers that manufacture, package, distribute, or direct ship a Walmart or Sam's Club product that is labeled under one of Walmart or Sam's Club's private brands, as follows:

- Items with a brand name or logo that is owned by Walmart or Sam's Club, such as Equate, Equate Beauty, or Member's Mark.
- Items with a brand name or logo that is exclusively licensed to Walmart or Sam's Club. In other words, these products are not offered at any other retailer in the U.S. or Puerto Rico.
- Unbranded items labeled as "Distributed by" or "Marketed by" Walmart or Sam's Club.

Direct Import ("DI") Suppliers:

Direct Import suppliers supply products under their own branding while Walmart or Sam's Club serves as the Importer of Record. These products are subject to the Walmart Supplier Agreement. These products may be exclusive to Walmart or Sam's Club or may be offered at other retailers in the U.S. or Puerto Rico.

National Brand Suppliers:

National brand suppliers resell their products at Walmart or Sam's Club under their own branding. These products are subject to the Walmart Supplier Agreement. These products may be exclusive to Walmart or Sam's Club or may be offered at other retailers in the U.S. or Puerto Rico.

Direct Ship Vendor ("DSV") Suppliers:

DSV suppliers sell their products on Walmart.com under their own branding and ship these products from their own facilities. These products are subject to the Walmart Supplier Agreement + DSV Schedule. These products may be exclusive to Walmart or may be offered at other retailers in the U.S. or Puerto Rico.

Any Supplier that enters into a Supplier Agreement and intends to supply Cosmetic Products must provide the information required under this policy to receive an approved Supplier Agreement. Supplying Cosmetic Products that do not comply with this policy may result in a termination of the Supplier Agreement and/or removal of the product(s) from Walmart and/or Sam's Club (stores or omnichannel).

The following requirements apply to Cosmetic Products supplied as Private Brands, Direct Import, National Brands, or DSV pursuant to a Supplier Agreement.

Supplier Requirements for Cosmetic Products

Health & Wellness Product Safety

What is a Cosmetic?

The FD&C Act defines cosmetics as "articles intended to be rubbed poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance." Examples of cosmetics include:

- **Baby Products** (e.g., baby shampoos, baby wipes, lotions, oils, powders, and creams)
- **Bath Preparations** (e.g., bath oils, bubble baths)
- **Eye makeup preparations** (e.g., eyebrow pencils, eyeliners, eye lotions, false lashes)
- **Children's eye makeup preparations** (e.g., children's eyeshadow, other eye makeup)
- **Fragrance preparations** (e.g., colognes, perfumes, powders)
- **Hair preparations (non-coloring)** (e.g., hair conditioners, hair sprays, rinses)
- **Hair coloring preparations** (e.g., hair dyes and colors, hair shampoos-coloring)
- **Makeup preparations (not eye)** (e.g., face powders, foundations, leg, and body paints)
- **Makeup preparations for children (not eye)** (e.g., children's face paints, lipsticks, color hairsprays)
- **Manicuring preparations** (e.g., cuticle softeners, nail creams, lotions, extenders, polishes, nail glue and false nails)
- **Oral products** (e.g., dentifrices, mouthwashes, other oral products)
- **Personal cleanliness** (e.g., bath soaps, body washes, underarm deodorants, disposable wipes)
- **Shaving preparations** (e.g., aftershave lotions, beard softeners, shaving creams)
- **Skin care preparations (creams, lotions, powder, and sprays)** (e.g., body and hand creams, foot sprays)
- **Suntan preparations** (e.g., suntan gels, creams, liquids)
- **Tattoo preparations** (e.g., permanent and temporary tattoo inks) or
- any substance intended for use as a component of a cosmetic product.

Certain traditional soap products are not considered cosmetics under the FD&C Act. However, most "soap" and other cleanser products are still considered cosmetics (or even drugs). For example, any "soap" product that moisturizes skin, includes deodorant, makes the user "smell nice," would be considered a cosmetic under the FD&C Act and would be subject to this policy.

Products intended as "grooming aids" for animals are not cosmetics regulated by FDA.

"Cosmetic tools and accessories" are "non-medical devices" that people use to affect their appearance." Examples include:

- **Hair grooming tools and accessories** (e.g., hair dryers, hair styling irons, razors, electric shavers, barrettes, combs, brushes, ponytails, bows, hair pins, curlers, etc.)
- **Nail and foot grooming and manicure tools** (e.g., nail clippers, nail files, foot exfoliation files)
- **Bath accessories** (e.g., bath brushes, exfoliation sponges and poofs, etc.)
- **Make-up applicators** (e.g., makeup brushes, sponges, pads, cotton balls, cotton pads, and other applicators)
- **Complexion tools** (e.g., gua sha and face rollers, blemish kits)

Cosmetic tools and accessories are ***not*** considered cosmetics and are instead regulated by the Consumer Product Safety Commission.

Cosmetics can be viewed by the US Food and Drug Administration (FDA) to be drugs or medical devices if they are intended to treat or cure a disease or to affect the structure or function of the body. Products that may also be regulated as an OTC drug or medical device must all meet all applicable state and federal regulations for drugs and medical devices as well as meet requirements noted in the Supplier Requirements for Over-the-Counter Drugs, Dietary Supplements, & Medical Devices policy. Examples include:

- **Acne treatments** (e.g., medicated acne washes, astringents, lotions, creams, ointments, and patches)
- **Deodorants that are also antiperspirants**
- **Moisturizers, lip balms, and makeup marketed with sun-protection claims.**
- **Antidandruff shampoo and treatments**
- **Hair removal and microdermabrasion devices** (e.g., laser hair removal devices, Microneedling Devices, etc.)

Do Cosmetics Require Approval by FDA?

No. But cosmetics are regulated by FDA. For example, FDA regulates the types of ingredients allowed in cosmetics and the types of claims that can be made about an ingredient and/or a product. FDA also regulates the manufacturing of cosmetics and requires the products be registered and listed with FDA.

Do Cosmetics need to comply with any legal requirements?

Yes. Cosmetics generally may be supplied to Walmart and Sam's Club if they comply with:

- The Federal, Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations and FDA guidance regarding cosmetics,
- Fair Packaging and Labeling Act
- State and local laws and regulations, and
- Relevant laws and guidance implemented by the FTC.

Cosmetics must meet specific requirements related to manufacturing, cosmetic labeling, safety reporting, and registration and listing with FDA as well as individual state and local laws and regulations. Only cosmetics that meet all requirements under the FD&C Act and state and local specific requirements may be supplied for sale by Walmart or Sam's Club. Some of these requirements come into effect on December 29, 2023, others will be phased in over time.

Labeling

Cosmetic Products must be labeled with an identity statement, indicating the nature and use of the product and an accurate statement of the net quantity of contents must appear on the principal display panel. Cosmetic packaging also must contain an information panel with 1) the name and place of business of the manufacturer, packer, or distributor; 2) Distributor statement; 3) Material facts or important directions; 4) Warning and caution statements; and 5) Ingredients listed in descending order of amounts used in the product. If the cosmetic product also contains OTC drug ingredients, its labeling must comply with the regulations for both OTC drug and cosmetic ingredient labeling as well as Walmart's policy for OTC Drugs.

Registration and Listing

Any person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States (US) must register each facility with FDA and renew such registration every two years. The entity whose name and identifying information appears on the product label must provide to FDA each

year certain "listing" information about each cosmetic product manufactured for US distribution.

Manufacturing

By the end of 2025, cosmetics will be required to be manufactured in accordance with Good Manufacturing Practices (GMPs). Cosmetic GMP regulations will establish quality requirements and standards for the manufacturing, packaging, labeling, and storing of cosmetic products.

Adverse Event Reporting

Manufacturers, packers, or distributors of cosmetic products whose name appears on the label of the cosmetic product must (1) report serious adverse events to the FDA within 15 days of receiving relevant information related to the serious adverse event, and (2) maintain records of adverse events. A serious adverse event is an adverse event resulting in death, a life-threatening experience, inpatient hospitalization, persistent/significant disability or incapacity, congenital anomaly or birth defect, infection, or significant disfigurement (serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent and significant alteration of appearance).

Safety Substantiation

Manufacturers, packers, or distributors of cosmetic products whose name appears on the label of the cosmetic product must ensure that the safety of each cosmetic product is supported by "adequate substantiation." Adequate substantiation of safety can be determined through tests, studies, research, analyses, or other evidence considered by experts with qualified training.

Small Business Exemptions

Certain "small businesses" are exempt from some of the facility registration, product listing, and GMP manufacturing requirements. A "small business" is an owner or operator of a cosmetics manufacturing facility with average gross annual sales of less than $1 million (inflation adjusted) for the previous three-year period, except if they are engaged in manufacturing or processing certain higher risk cosmetic products, including:

- Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.
- Cosmetic products that are injected.
- Cosmetic products that are intended for internal use.
- Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

What Requirements Apply to Cosmetic Products Supplied to Walmart and Sam's Club?

All Suppliers of Cosmetic Products must ensure that their products meet all legal and regulatory requirements, including requirements under the FD&C Act and FDA's regulations and guidance as well as applicable state and local laws and regulations. Cosmetic Products that do not follow FDA's regulations, such as not having adequate safety substantiation, lacking FDA product listing, or that are not manufactured in an FDA-registered facility may be considered misbranded or adulterated and unlawful to sell in the US.

National Brand and DSV Suppliers must meet all requirements set out below and complete a third-party Cosmetic, Beauty, and Personal Care Protocol Review with a Walmart approved third-party review lab prior initial business and annually thereafter.

Private Brand and Direct Import Suppliers of Cosmetic Products must undergo a full review and verification of all labeling artwork and meet all of the requirements set out below.

Facility Disclosure and Registration

Suppliers of Cosmetic Products must disclose to Health & Wellness Product Safety each facility that engages in the manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of such products. This includes all subcontracted facilities or any operations and facilities that are not owned by the Supplier, but from which products are sourced. Once approved, Suppliers are responsible for disclosing any new facility to Health & Wellness Product Safety. **Private Brand and Direct Import Suppliers must receive facility approval from Health & Wellness Product Safety**

prior to production of Cosmetic Products in that facility.

All Cosmetic Products sold in the US must be manufactured in facilities registered with FDA, with such registration being renewed every two years. Facility information provided to Health & Wellness Product Safety must match the information in the FDA FEI Search Portal and must remain accurate. **National Brand and DSV Suppliers** must provide proof of FDA registration when completing the third-party Cosmetic, Beauty, and Personal Care Protocol Review with a Walmart approved third-party review lab prior initial business and annually thereafter.

Private Brand and Direct Import Suppliers must provide FDA cosmetic registration information to Walmart Health & Wellness Product Safety prior to supplying product and on an annual basis going forward. Email Health & Wellness Product Safety at HWSCSAFETY@wal-mart.com to obtain the appropriate facility information form.

State Requirements

Certain states have licensing and registration requirements beyond federal registration requirements. All Suppliers of Cosmetic Products are responsible for ensuring compliance with applicable state laws. Suppliers are responsible for completing and submitting all licensing and registration forms and paying all licensing and registration fees on or before any applicable deadline. **National Brand and DSV Suppliers** must provide proof of any state registrations when completing the third-party Cosmetic, Beauty, and Personal Care Protocol Review with a Walmart approved third-party review lab prior initial business and annually thereafter. **Private Brand and Direct Import Suppliers must submit proof of any state registrations for applicable facilities to Walmart Health & Wellness Product Safety prior to supplying product as well as when those licenses are renewed.**

Cosmetic Product Listing and State Registration

As of July 1, 2024, all Cosmetic Products must be listed with FDA. The entity whose name and identifying information appears on the product label is considered by FDA to be the "responsible person." The responsible person must provide to FDA each year certain "listing" information about each cosmetic product manufactured for US distribution.

Walmart is the "responsible person" for Private Brand Cosmetic Products labeled as being distributed by Walmart Inc., or Sam's West, Inc. **All suppliers for Private**

Brand Cosmetic Products must provide all necessary information to support Walmart's obligations to list Private Brand Cosmetic Products.

Suppliers of Cosmetic Products must comply with all state and local product registration requirements. **National Brand and DSV Suppliers** must provide proof of required product listing and state registrations when completing the third-party Cosmetic, Beauty, and Personal Care Protocol Review with a Walmart approved third-party lab prior to initial business and annually thereafter. **Private Brand and Direct Import Suppliers must provide proof of required state and local registrations to Health & Wellness Product Safety upon initial registration and annually thereafter.**

Good Manufacturing Practices

Walmart expects suppliers to provide proof of conformance with voluntary industry recognized standards of quality and GMPs for the manufacturing, packaging, labeling, and storing of Cosmetic Products. By the end of 2025, cosmetics will be required to be manufactured in accordance with FDA-issued GMPs. Cosmetic GMP regulations will establish quality requirements and standards for the manufacturing, packaging, labeling, and storing of cosmetic products.

All Cosmetic Products supplied must be manufactured in facilities that are in good standing with FDA (i.e., not "Official Action Indicated" and no outstanding significant 483s). Suppliers may provide the information that is available on the FDA website as evidence of a satisfactory compliance status for manufacturing facilities. In addition, if the status of a manufacturing facility is "Voluntary Action Indicated" or there is an outstanding 483, suppliers must provide a copy of the Establishment Inspection Report, 483, and Supplier's response.

Third Party Certification and Annual Audit

National Brand and DSV Suppliers of Cosmetic Products must provide a certification of conformance with voluntary GMPs such as a letter from the Supplier's Head of Quality or from a third-party auditor, for each facility involved in the manufacturing process for Cosmetic Products supplied to Walmart or Sam's Club. Certificate of Conformance must be provided when completing the third-party Cosmetic, Beauty, and Personal Care Protocol Review with a Walmart approved third-party lab prior to initial business and annually thereafter.

Private Brand and Direct Import Suppliers of Cosmetic Products must provide to Health & Wellness Product Safety full reports of third-party GMP audits showing conformance with voluntary GMPs for each facility involved in the manufacturing process for Cosmetic Products supplied to Walmart or Sam's Club. Additional audits may also be required by Walmart's Responsible Sourcing team. The third-party audit firms approved by Walmart for Private Brand and Direct Import Suppliers are provided in the **Approved Third-party GMP Audit Information.**

Audits must have been conducted within the previous rolling 12-month time frame and be reviewed and approved by Health & Wellness Product Safety. Items showing non-conformance to standards will require submission of corrective measures acceptable to Health & Wellness Product Safety to receive approval. Additional conformance audits may be required. Once approved, Suppliers will be responsible for providing updated conformance audit and certification documentation to Health & Wellness Product Safety annually. Additionally, GMP conformance audits must occur on or before the one-year anniversary of when the last audit was conducted and be sent to Health & Wellness Product Safety at HWAudits@walmart.com on or before the anniversary of the preceding audit. You may email HWSCSAFETY@wal-mart.com should you have any questions regarding GMP audit and certification conformance.

Labeling

All Cosmetic Products must comply with FDA regulations and guidance, Fair Packaging and Labeling Act, as well as all state specific labeling requirements. Cosmetic Products must contain an identity statement, indicating the nature and use of the product and an accurate statement of the net quantity of contents must appear on the principal display panel. Cosmetic packaging also must contain an information panel with:

- The name and place of business of the manufacturer, packer, or distributor.
- Distributor statement.
- Materials fact or important directions.
- Warning and caution statements; and
- Ingredients listed in descending order of amounts used in the product.

If the Cosmetic Product also contains OTC drug ingredients, its labeling must comply with the regulations for both OTC drugs and cosmetics as well as Walmart's policy for OTC drugs. Please refer to the Resource section of this document for additional references.

Private Brand and Direct Import Cosmetic Products will undergo a full labeling review by Walmart.

Packaging

Cosmetic Oral Hygiene and Vaginal Products must be packaged in tamper-resistant packaging, in accordance with applicable regulations. The packaging must use an indicator or barrier to entry that is distinctive by design, or must employ an identifying characteristic (a pattern, name, registered trademark, logo, or picture). Further, the regulations require a labeling statement on the container to alert the consumer to the specific tamper-resistant feature(s) used. The labeling statement is also required to be placed so that it will be unaffected if a TRP feature is breached or missing.

Suppliers must ensure that their orally administered products comply with the requirements of the Poison Prevention Packaging Act, including, where applicable, the use of child resistant caps. **National Brand and DSV Suppliers** must provide a current General Certificate of Conformity for each size container of a Cosmetic Product with a child-resistant cap when completing the third-party Cosmetic, Beauty, and Personal Care Protocol Review with a Walmart approved third-party lab prior to initial business and annually thereafter. **Private Brand and Direct Import Suppliers must provide to Health & Wellness Product Safety a current General Certificate of Conformity for each size container of a Cosmetic Product with a child-resistant cap prior to initial manufacturing with each container and annually thereafter.** Certificates of Conformity should reference the requirements for special packaging, 16 CFR 1700.14 and 1700.15.

Cosmetic Products are also subject to Country of Origin labeling requirements per U.S. Customs and Border Protection.

Private Brand and Direct Import Cosmetic Products will undergo a full packaging review by Walmart.

Safety Substantiation

Beginning December 29, 2023, the manufacturer, packer, marketer, or distributor whose name appears on the label of a Cosmetic Product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of the cosmetic product. Adequate safety substantiation includes but may not be limited to tests or studies,

research, analyses, or other evidence or information considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support with reasonable certainty the cosmetic product is not injurious to users when used as intended.

Private Brand and Direct Import Cosmetic Products will undergo a safety substantiation review by Walmart.

Adverse Event Reporting

Beginning December 29, 2023, the manufacturer, packer, marketer, or distributor whose name appears on the label of a Cosmetic Product is responsible for reporting to FDA "serious adverse events," within 15 business days of receipt of a report of such an event. A serious adverse event is an adverse event resulting in death, a life-threatening experience, inpatient hospitalization, persistent/significant disability or incapacity, congenital anomaly or birth defect, infection, or significant disfigurement (serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent and significant alteration of appearance).

All Suppliers of Cosmetic Products must have Standard Operating Procedures (SOPs) in place or otherwise ensure compliance with federal adverse event reporting and record-keeping requirements. If Walmart receives an adverse event report via the Walmart Care Center, it will be immediately forwarded to the supplier.

Suppliers of Private Brand and Direct Import Cosmetic Products must support Walmart's obligations to meet serious adverse event reporting requirements.

Product complaints that are not adverse events or serious adverse events, but that may affect product safety or quality, such as foreign objects or tampering, must be reported by Suppliers to Health & Wellness Product Safety via email at HWSCSAFETY@wal-mart.com.

Claims

All claims on cosmetic labels must be truthful and not misleading. Cosmetics should not claim to treat or prevent diseases, health conditions, or affect the structure or function of the body. For example, a skincare product that claims to reduce the appearance of wrinkles is a cosmetic; but a skincare product that claims to eliminate wrinkles, may be viewed by FDA as a drug (because it is claiming to change the structure of the skin).

The Federal Trade Commission (FTC) in the US regulates the advertising of cosmetics. FTC also requires that claims for cosmetics be truthful and not misleading. Problematic claims for cosmetics include things like promising a specific improvement in appearance ("Reduce Wrinkles by 99 percent"), claiming permanent or long-lasting results ("permanently reduce the appearance of cellulite;" "results just as good as liposuction"), and using fake or misleading before and after images. FTC also looks carefully at whether claims made about cosmetics are adequately substantiated, meaning there is enough evidence to support them. For example, FTC has been focused on the use of "natural" or "clean" claims made in the cosmetics industry. To make these kinds of claims, products must have and rely on competent and reliable scientific evidence to support such claims.

Private Brand and Direct Import OTC Drugs will undergo a claim substantiation review by Walmart.

Prohibited Cosmetic, Beauty, and Personal Care Products

Cosmetic products that may be considered unsafe, as determined by a federal or state agency (e.g., FDA) are prohibited. Walmart also has the discretion to determine that cosmetics or ingredients are not safe for consumers generally or for a specific subpopulation of consumers. For example:

- Any product that purports to be a cosmetic but that implicitly or explicitly claims, in labels, labeling or advertising, to diagnose, cure, mitigate, treat, or prevent diseases, illnesses, ailments, infections, or viruses is prohibited. These products are considered by FDA to be unapproved drugs.
- Cosmetic products that require a prescription, that are designed for professional use only, or that contain ingredients that are unsafe for the consumer are prohibited.
- Cosmetics containing prohibited or restricted substances, or ingredients:
- Cosmetics that contain color additives that are not permitted for use in cosmetics[1]
- Cosmetics identified in FDA Warning Letters
- Cosmetics that contain ingredients from prohibited or protected/restricted animals/mammals (e.g., snake venom, squalene) and/or that contain animal parts (e.g., mink fur eyelashes, etc.)

[1] See Appendix A for a list of color additives permitted for use in cosmetics, including a list of color additives permitted for use with certification.

- Cosmetics that contain illegal/restricted plants, plant products, or seeds as determined by federal, state, or local government.
- Cosmetics that require refrigeration or that are temperature sensitive.
- Cosmetics that have been tested on animals.
- Cosmetics intended for use in any area of the body containing added mercury.
- Cosmetics and Personal Care Products containing 1,4 Dioxane in excess of allowed limits as cited in NY CLS Section 37-0117.
- Cosmetic and Personal Care Products containing natural or synthetic cannabidiol, CBD, CPG, THC, Delta-8 tetrahydrocannabinol.
- Unsafe cosmetics (e.g., skin bleaching products) including but not limited to cosmetics containing:
    - **Bithionol.**
    - **Chlorofluorocarbon propellants.**
    - **Chloroform.**
    - **Halogenated salicylamides (di-, tri-, metabromsalan and tetrachlorosalicylanilide).**
    - **Hexachlorophene.**
    - **Mercury compounds.**
    - **Methylene chloride.**
    - **Prohibited cattle materials.**
    - **Sunscreens in cosmetics.**
    - **Vinyl chloride.**
    - **Zirconium-containing complexes.**
- "Rinse-off" cosmetics that do not comply with the Microbead-Free Waters Act
- Cosmetics intended for coloring hair on the scalp containing Lead Acetate.
- Cosmetics, Beauty, and Personal Care Children's products containing formaldehyde and/or formaldehyde donor chemicals.
- Stay-on Cosmetics, excluding lip products, containing lead content in excess of 10 ppm by weight.
- Lip Products containing total lead content in excess of 5 ppm by weight.

Cosmetic Product Recalls and Removals

Health and Wellness Product Safety

Walmart and Sam's Club adhere to strict quality standards, and we collaborate with our Suppliers to ensure that we provide safe, quality products. However, sometimes product removals and corrections may be necessary in the event of a withdrawal or recall.

Product removals are initiated by the supplier or regulatory agency and at their request are executed by the Walmart and Sam's Club. In some cases, however, a product removal may be initiated by Walmart or Sam's Club due to internal information (e.g., customer complaints, test results, etc.). If you become aware of a safety or quality issue with any product or ingredients used in any product sold at Walmart or Sam's Club, immediately contact the Health & Wellness Product Safety at HWRECALLS@walmart.com.

Recalls, Corrections, and Removal Notices:

Recalls are due to a Supplier's removal of a marketed product that violates laws or regulations and that would be subject to legal action from a regulator, e.g., seizure. A Supplier may choose to remove or correct a distributed product for any reason and under any circumstance. A recall or correction does not include a market withdrawal or a stock recovery. Examples of reasons to recall products include but are not limited to product that does not meet product specification, fails to have required warnings, or packaging does not meet child safety requirements. These products may pose a potential safety risk if consumed or used.

FDA-related recalls are classified into three categories (I, II, or III) to indicate the relative degree of health hazard presented by the product being recalled.

- **Class I** - a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- **Class II** - a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III** - a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

If a recall has been classified by FDA, the supplier must share the classification and other necessary information with the Walmart immediately to allow Walmart and/or Sam's Club

to execute the recall. Suppliers must complete and submit the Product Removal Form in Retail Link using the following path:

Retail Link > Apps > Product Removal > Create New > Walmart or Sam's Club

Withdrawals

Market withdrawals are due to a Supplier's removal or correction of a distributed product involving a minor violation that would not be subject to regulatory action or that involves no violation, e.g., business reasons, normal stock rotation practices, routine equipment adjustments and repairs, etc.

If a product removal is necessary for one of your products or if you have any concerns regarding the safety of any of your products, immediately contact Health & Wellness Product Safety at HWRECALLS@walmart.com and submit a Product Removal Form in Retail Link using the following path:

Retail Link > Apps > Product Removal > Create New > Walmart or Sam's Club.

Recall or Withdrawal Process

Suppliers should have the following information ready when contacting the Walmart Corporate Compliance Recall Team about a recall or withdrawal:

- Reason for the removal.
- Item number/UPC number or NDC number (when applicable).
- Lot code/expiration dates.
- Store/Club distribution list that received the implicated product.
- List of any Walmart Distribution Centers that received the impacted product.
- Disposition and handling instructions for the product.
- A copy of any press releases the Supplier, or a regulatory agency will issue regarding the recall.

All recalls, corrections, and removals are managed centrally by Health & Wellness Product Safety. All impacted facilities will promptly be notified using the information that you have provided. Suppliers must immediately initiate the removal process by completing a

Product Removal Form in Retail Link using the following path.

Retail Link > Apps > Product Removal > Create New > Walmart or Sam's Club.

Supplier Resources

Health and Wellness Product Safety

Resources and References

Federal Food, Drug, and Cosmetic Act and FDA regulations
FDA Cosmetics Labeling Guide
FTC Health Products Compliance Guide
FDA Website Cosmetic Page
Warning Letters Highlight Differences Between Cosmetics and Medical Devices.

Approved Third-Party GMP Audit and Certification Bodies For Private Brand and Direct Import Cosmetic, Beauty, and Personal Care Products

Third-party voluntary quality or GMP conformance audit documents, GMP Certificates, and Corrective Action Plan (CAP) documents for third-party GMP audit non-conformances should be emailed to HWAudits@walmart.com.

Product Category	Third-party Audit Program	Audit Standard
Nonprescription Cosmetic Products	SGS ISO 22716 Certification-Cosmetic GMP NSF/ANSI 455-3 Cosmetic GMP Certification UL ISO-22716-2007 Certification Intertek ISO 22716 Good Manufacturing Practices for Cosmetics BSI ISO 22717 Good Manufacturing Practices for Cosmetics	ISO 22716 U.S. FDA Cometic Guidelines

Appendix A. Color Additives Permitted for Use in Cosmetics

For additional and the most up-to-date information on the permitted use, specifications, and restrictions that apply to each color additive, please refer to FDA's regulations on the use of color additives in cosmetics (21 CFR Part 73 Subpart C – Cosmetics, Part 74 Subpart C – Cosmetics, and Part 82 Subparts B, C, D), and FDA's Fact Sheet on Color Additives and Cosmetics (https://www.fda.gov/industry/color-additives-specific-products/color-additives-and-cosmetics-fact-sheet).

Table 1. Color Additives that are Exempt from Certification and Permitted for Use in Cosmetics

Color Additive	Eye Area	Generally, (Includes Lipsticks)	External Use	Specific Limitations and Comments
Aluminum powder	Yes	No	Yes	
Annatto	Yes	Yes	Yes	
Bismuth citrate	No	No	Subject to limitations	Hair on the scalp
Bismuth oxychloride	Yes	Yes	Yes	
Bronze powder	Yes	Yes	Yes	
Caramel	Yes	Yes	Yes	
Carmine	Yes	Yes	Yes	
β-Carotene	Yes	Yes	Yes	
Chromium hydroxide green	Yes	No	Yes	
Chromium oxide greens	Yes	No	Yes	

Color Additive	Eye Area	Generally, (Includes Lipsticks)	External Use	Specific Limitations and Comments
Copper powder	Yes	Yes	Yes	
Dihydroxyacetone	No	No	Subject to limitations	For use in tanning preparations
Disodium EDTA-copper	No	No	Subject to limitations	Shampoos
Ferric ammonium ferrocyanide	Yes	No	Yes	
Ferric ferrocyanide	Yes	No	Yes	
Guaiazulene	No	No	Yes	
Guanine	Yes	Yes	Yes	
Henna	No	No	Subject to limitations	Hair on the scalp
Iron oxides	Yes	Yes	Yes	
Luminescent zinc sulfide	No	No	Subject to limitations	Externally applied facial makeup and nail polish; <10%; for="" infrequent="" use="" (e.g., ="">
Manganese violet	Yes	Yes	Yes	
Mica	Yes	Yes	Yes	
Potassium sodium copper chlorophyllin (chlorophyllin-copper complex)	No	No	Subject to limitations	Dentifrices; ≤0.1%

Color Additive	Eye Area	Generally, (Includes Lipsticks)	External Use	Specific Limitations and Comments
Pyrophyllite	No	No	Yes	
Silver	No	No	Subject to limitations	Fingernail polish; ≤1%
Silver nitrate	Yes	No	No	Externally applied professional-use only cosmetics intended to impart color to the eyebrows and eyelashes, NTE 4% by weight, additional restrictions
Titanium dioxide	Yes	Yes	Yes	
Ultramarines	Yes	No	Yes	
Zinc oxide	Yes	Yes	Yes	

Table 2. Color Additives that are Subject to Certification and Permitted for Use in Cosmetics*

Color Additive	Eye Area**	Generally, (Includes Lipsticks)	External Use	Specific Limitations and Comments
D&C Black No. 2	Subject to Limitations	Subject to Limitations	Subject to Limitations	Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers & rouge, makeup & foundation, nail enamel
D&C Black No. 3	Subject to Limitations	No	Subject to Limitations	Eyeliner, eye shadow, mascara, face powder
FD&C Blue No. 1	Yes, also Al lake	Yes	Yes	

Color Additive	Eye Area**	Generally, (Includes Lipsticks)	External Use	Specific Limitations and Comments
D&C Blue No. 4	No	No	Yes	
D&C Brown No. 1	No	No	Yes	
FD&C Green No. 3	No	Yes	Yes	
D&C Green No. 5	Yes	Yes	Yes	
D&C Green No. 6	No	No	Yes	
D&C Green No. 8	No	No	Subject to Limitations	≤0.01%
D&C Orange No. 4	No	No	Yes	
D&C Orange No. 5	No	Subject to Limitations	Yes	Mouthwashes, dentifrices; ≤5% for lipsticks
D&C Orange No. 10	No	No	Yes	
D&C Orange No. 11	No	No	Yes	
FD&C Red No. 4	No	No	Yes	
D&C Red No. 6	No	Yes	Yes	
D&C Red No. 7	No	Yes	Yes	
D&C Red No. 17	No	No	Yes	
D&C Red No. 21	No	Yes	Yes	
D&C Red No. 22	No	Yes	Yes	
D&C Red No. 27	No	Yes	Yes	

Color Additive	Eye Area**	Generally, (Includes Lipsticks)	External Use	Specific Limitations and Comments
D&C Red No. 28	No	Yes	Yes	
D&C Red No. 30	No	Yes	Yes	
D&C Red No. 31	No	No	Yes	
D&C Red No. 33	No	Subject to Limitations	Yes	Lipstick products ≤3%; mouthwash, dentrifices
D&C Red No. 34	No	No	Yes	
D&C Red No. 36	No	Subject to Limitations	Yes	Lipstick products ≤3%
FD&C Red No. 40	Yes, also Al lake	Yes	Yes	
D&C Violet No. 2	No	No	Yes	
Ext. D&C Violet No. 2	No	No	Yes	
FD&C Yellow No. 5	Yes, also Al lake	Yes	Yes	
FD&C Yellow No. 6	No	Yes	Yes	
D&C Yellow No. 7	No	No	Yes	
Ext. D&C Yellow No. 7	No	No	Yes	
D&C Yellow No. 8	No	No	Yes	

Color Additive	Eye Area**	Generally, (Includes Lipsticks)	External Use	Specific Limitations and Comments
D&C Yellow No. 10	No	Yes	Yes	
D&C Yellow No. 11	No	No	Yes	

*Includes straight colors and lakes.

**Excludes lakes except where noted. Only aluminum lakes on alumina are permitted for designated lakes.