



# Supplier Requirements for Over-the-Counter Drugs, Dietary Supplements, & Medical Devices

Health & Wellness Product Safety

## Purpose

The requirements described in this document apply to anyone that supplies product, 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 Over-the-Counter (“OTC”) drugs, OTC homeopathic products, dietary supplements, and consumer medical devices (“Health and Wellness 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 Health and Wellness Products.

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 Health and Wellness 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 and Sam’s Club reserve 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 Health and Wellness 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 Health & Wellness Products supplied to Walmart or Sam’s Club are subject to these requirements, please contact Health & Wellness Product Safety at [HWSCSAFETY@ wal-mart.com](mailto:HWSCSAFETY@wal-mart.com)

## Health and Wellness 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 or Member's Mark.
- Items with a brand name or logo that are exclusively licensed to Walmart or Sam's Club, such as Spring Valley. 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 and/or Samsclub.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 Sam's Club or may be offered at other retailers in the U.S. or Puerto Rico.

## Supplier Requirements for Health and Wellness Products | Private Brand, National Brand, and DSV Suppliers

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

Failure to comply with all federal, state, and local regulatory requirements as described in this document and otherwise applicable to a Health and Wellness 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.

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



# Supplier Requirements for Over-the-Counter Drugs

Health & Wellness Product Safety

## What is an OTC drug?

OTC drugs are sold directly to consumers without a prescription. Like prescription drugs, OTC drugs are regulated by FDA. All OTC drugs must have a Drug Facts Label that instructs consumers on how to properly choose and use them. OTC Drugs treat many common ailments including pain, fever, cough and cold, upset stomach, and allergies. OTC Drugs should not be confused with dietary supplements (vitamins, minerals, herbals, and botanicals), which have different rules.

## Can Some OTC Drugs Be Marketed Without FDA Approval?

Yes. Any OTC drug product that conforms to an OTC monograph may be manufactured and sold without submitting an application for approval to FDA. A searchable list of all OTC monographs can be found [on FDA's Website](#). A monograph is a regulatory standard for the labeling and ingredients for products within a specific category such as antacids, analgesics, etc. It is a kind of "recipe book" covering acceptable ingredients, doses, formulations, indications, and labeling.

Some OTC medicines do not fall within the monograph system and require approval via a new drug application (NDA) or Abbreviated New Drug Application (ANDA).

## What Requirements Apply to OTC Drugs Supplied to Walmart?

All Suppliers of OTC drugs must ensure that their products meet all legal and regulatory requirements, including requirements under the Federal Food, Drug and Cosmetic Act (FD&C Act) and FDA's regulations and guidance. OTC Drugs that do not follow FDA's regulations, such as by not having a valid Drug Facts Label, or that are not manufactured in an FDA-registered facility may be considered misbranded or adulterated and unlawful to sell in the U.S. **Suppliers of Private Brand and Direct Import OTC Drugs will undergo a full review and verification of all labeling artwork in addition to the requirements set out below.**

# Legal and Regulatory Requirements for OTC Drugs:

## Facility Disclosure and Registration

Suppliers of OTC Drugs 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 OTC Drugs are sourced. Once approved, Suppliers are responsible for disclosing any new facility to Health & Wellness Product Safety. Private Brand and Direct Import Suppliers of OTC Drugs must receive facility approval **prior** to supplying OTC drug products produced in that facility.

All OTC Drugs sold in the U.S. must be manufactured in facilities registered with FDA. Facility information provided to Health & Wellness Product Safety must match the information on the FDA [Drug Establishments](#) Registration Site and must remain accurate. Suppliers must provide FDA drug registration information to 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](mailto:HWSCSAFETY@wal-mart.com) to obtain the appropriate facility information form.

## State Requirements

Certain states have licensing and registration requirements above and beyond federal registration requirements. All Suppliers of OTC Drugs are responsible for ensuring compliance with applicable state laws.

Suppliers must submit proof of any state registrations to Health & Wellness Product Safety prior to supplying product as well as when those licenses are renewed. 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.

## Drug Listing

All OTC Drugs manufactured in FDA-registered facilities must also be listed with FDA. All Suppliers of OTC Drugs are required to ensure that their products have been appropriately listed with FDA. The FDA drug listing must match the name of the OTC Drug supplied.

## Current Good Manufacturing Practices (CGMPs)

All OTC Drugs supplied must be manufactured in facilities that are in good standing with FDA (i.e. not “Official Action Indicated” and no outstanding significant 483s) and manufactured in accordance with FDA’s CGMPs. 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 OTC Drugs marketed under an OTC monograph (not approved under NDAs or ANDAs) must provide to Health & Wellness Product Safety a certification of conformance with CGMPs, 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 an OTC Drug supplied to Walmart or Sam's Club.

**Private Brand and Direct Import Suppliers** of OTC Drugs marketed under an OTC monograph (not approved under NDAs or ANDAs) must provide to Health & Wellness Product Safety full reports of third-party CGMP audits showing conformance with CGMPs for each facility involved in the manufacturing process for an OTC Drug supplied to Walmart or Sam's Club. Additional social audits may also be required by Walmart's Responsible Sourcing team. The third-party audit firms approved by Health & Wellness Product Safety for Private Brand and Direct Import are provided in the [Approved Third-party CGMP 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, CGMP 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 on or before the anniversary of the preceding audit. You may email [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) should you have any questions regarding CGMP audit and certification conformance.

## **Marketing Authorization**

Suppliers must have the right to market any OTC Drugs requiring marketing authorization under an approved NDA or ANDA.

Any OTC Drug that is subject to an OTC Monograph must be marketed in accordance with that OTC Monograph. Suppliers must certify compliance with the applicable OTC Monograph.

## **Labeling**

All OTC Drugs must comply with FDA regulations and guidance regarding OTC Drug labeling including:

- bearing a net quantity of contents statement;
- identifying the name and address of the manufacturer, distributor, or packer;
- containing information for the reporting of serious adverse events;
- containing a Drug Facts Label with all required information (e.g., purpose, uses/indications/directions/warnings);



- containing the active ingredients, including the amount in each dosage unit; and
- containing a list of the inactive ingredients.

OTC Drugs subject to an approved NDA or ANDA must be labeled in accordance with the FDA-approved labeling.

OTC Drugs subject to an OTC Monograph must meet the general regulatory requirements for OTC labeling and any specific labeling requirements of the relevant OTC Monograph.

**Private Brand and Direct Import OTC Drugs** will undergo a full labeling review by Health & Wellness Product Safety.

### **Packaging**

Most OTC Drugs 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 (such as an aerosol container), or must employ an identifying characteristic (a pattern, name, registered trademark, logo, or picture). Further, the regulations require a labeling statement on the container (except ammonia inhalant in crushable glass ampules, aerosol products, or containers of compressed medical oxygen) 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. The following products are excepted from these requirements: dermatologics, dentifrices, insulin and throat lozenges (21 CFR 211.132); cosmetic liquid oral hygiene products and vaginal products (21 CFR 700.25); and contact lens solutions and tablets used to make these solutions (21 CFR 800.12).

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. Suppliers must provide to Health & Wellness Product Safety a current General Certificate of Conformity for each size container of an OTC drug 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.

OTC Drugs are also subject to Country of Origin labeling requirements per U.S. Customs and Border Patrol.

**Private Brand and Direct Import OTC Drugs** will undergo a full packaging review by Health & Wellness Product Safety.

### **Adverse Event Reporting**

The manufacturer, packer, or distributor whose name appears on the label of an OTC Drug is responsible for reporting to FDA “serious adverse events,” within 15 business days of receipt of a report of such an event. All Suppliers of OTC drugs must have Standard Operating Procedures

(SOPs) in place or otherwise ensure compliance with federal adverse event reporting requirements. If Walmart receives an adverse event report via the Walmart Care Center, it will be immediately forwarded to the supplier.

Suppliers of OTC Drugs must inform Health & Wellness Product Safety via email at [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) of any customer reports of adverse events or serious adverse events within 48 hours of receiving such report.

**Suppliers of Private Brand and Direct Import OTC Drugs** must submit to FDA, on behalf of Walmart and/or Sam's Club, serious adverse event reports within 15 business days of receipt of the initial complaint. Health & Wellness Product Safety must be copied on all serious adverse event reports submitted to FDA on its behalf as well as all follow-up reports of additional information submitted to FDA on behalf of Walmart and/or Sam's Club.

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 or via email at [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com).

**Suppliers of Private Brand and Direct Import OTC Drugs** are responsible for investigating product complaints and must provide information regarding the investigative outcome to Health & Wellness Product Safety upon completion.

## **Claims**

Health-related advertising claims about Health and Wellness Products, which include claims in an online product description, are regulated primarily by the Federal Trade Commission (FTC). Statements made about Health and Wellness Products must be truthful and not misleading and must have adequate substantiation by competent and reliable scientific evidence. FTC's [Health Products Compliance Guidance](#) is a helpful tool for figuring out what kinds of claims and substantiation are appropriate for Health and Wellness Products. Claims about OTC drugs must be consistent with the use described in the Drug Facts Labeling.

**Private Brand and Direct Import OTC Drugs** will undergo a substantiation review by Health & Wellness Product Safety.

# OTC Homeopathic Drugs

## What are Homeopathic Drugs?

OTC Homeopathic Drugs are derived from botanical, mineral or biological substances. The theory of homeopathy is that homeopathic products are more effective when they are diluted. These products are usually diluted with purified water or an alcohol solution.

## Are Homeopathic Drugs Regulated by the FDA?

FDA classifies homeopathic products as drugs, but regulates them via enforcement discretion, meaning they are not reviewed or approved by FDA. Instead, FDA has identified in guidance the types of homeopathic products that would be subject to FDA regulatory enforcement or action. FDA has specifically identified categories of homeopathic products that the Agency will prioritize for regulatory enforcement, such as those intended for populations at greater risk for adverse reactions. OTC homeopathic medicines must be indicated for similar conditions as OTC drugs. These conditions can be self-diagnosed and are generally not chronic in nature, for example the common cold, upset stomach, or minor aches and pains.

## What Requirements Apply to OTC Homeopathic Drugs Supplied to Walmart and Sam's Club?

### Pharmacopoeia Certification

Suppliers must ensure that individual homeopathic ingredients supplied to Walmart or Sam's Club for sale in OTC Homeopathic Drugs in the U.S. have been reviewed for homeopathic efficacy, toxicology, adverse effects, and clinical use by the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) and are listed (monographed) in the Homeopathic Pharmacopoeia of the United States (HPUS). Listing in the HPUS is not a certification that a homeopathic product is safe, effective, and not misbranded for its intended use.

### Labeling

All OTC Homeopathic Drugs must comply with FDA regulations and guidance regarding OTC Drug labeling including:

- bearing a net quantity of contents statement;
- identifying the name and address of the manufacturer, distributor, or packer;
- containing information for the reporting of serious adverse events;
- containing a Drug Facts Label with all required information (e.g., purpose, uses/indications/directions/warnings);
- containing the active ingredients, including the amount in each dosage unit;
- and

- containing a list of the inactive ingredients.

The potency must be included on the product label immediately following the product name and include a number, followed either by an X or a C, to show the number of times the medicine was diluted and the ratio of the dilution (i.e., 1/10 for X and 1/100 for C).

**Private Brand and Direct Import OTC Homeopathic Drugs** will undergo a labeling review by Health & Wellness Product Safety.

### **Packaging**

Most OTC Homeopathic Drugs 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 (such as an aerosol container), or must employ an identifying characteristic (a pattern, name, registered trademark, logo, or picture). Further, the regulations require a labeling statement on the container (except ammonia inhalant in crushable glass ampules, aerosol products, or containers of compressed medical oxygen) 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. The following products are excepted from these requirements: dermatologics, dentifrices, insulin and throat lozenges (21 CFR 211.132); cosmetic liquid oral hygiene products and vaginal products (21 CFR 700.25); and contact lens solutions and tablets used to make these solutions (21 CFR 800.12).

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. Suppliers must provide to Health & Wellness Product Safety a current General Certificate of Conformity for each size container of an OTC homeopathic drug 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.

OTC homeopathic Drugs are also subject to Country of Origin labeling requirements per U.S. Customs and Border Patrol.

**Private Brand and Direct Import OTC Homeopathic Drugs** will undergo a packaging review by Health & Wellness Product Safety.

Suppliers of OTC Homeopathic Drugs 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 OTC Homeopathic Drugs 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 prior to supplying OTC Homeopathic Drugs produced in that facility.**

All OTC Homeopathic Drugs sold in the U.S. must be manufactured in facilities registered with FDA. Facility information provided to Health & Wellness Product Safety must match the information on the FDA [Drug Establishments Registration Site](#) and must remain accurate. Suppliers must provide FDA drug registration information to 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](mailto:HWSCSAFETY@wal-mart.com) to obtain the appropriate facility information form.

### **Current Good Manufacturing Practices**

All OTC Homeopathic Drugs supplied must be manufactured in facilities that are in good standing with FDA (i.e., not “Official Action Indicated” and no outstanding significant 483s) and manufactured in accordance with FDA’s CGMPs. 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 OTC Homeopathic Drugs must provide to Health & Wellness Product Safety a certification of conformance with CGMPs, 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 an OTC Homeopathic Drug supplied to Walmart or Sam’s Club.

**Private Brand and Direct Import Suppliers** of OTC Homeopathic Drugs must provide to Health & Wellness Product Safety full reports of third-party CGMP audits showing conformance with CGMPs for each facility involved in the manufacturing process for an OTC Homeopathic Drug supplied to Walmart or Sam’s Club. Additional social audits may also be required by Walmart’s Responsible Sourcing team. The third-party audit firms approved by Walmart are provided in the [Approved Third-party CGMP 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, Supplier will be responsible for providing updated conformance audit and certification documentation to Health & Wellness Product Safety annually. Additionally, CGMP 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](mailto:HWAudits@walmart.com) on or before the anniversary of the preceding audit. You may email [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) should you have any questions regarding CGMP audit and certification conformance.

## Adverse Event Reporting

The manufacturer, packer, or distributor whose name appears on the label of an OTC Homeopathic Drug is responsible for reporting to FDA “serious adverse events,” within 15 business days of receipt of a report of such an event. All Suppliers of OTC Homeopathic drugs must have SOPs in place or otherwise ensure compliance with federal adverse event reporting 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 OTC Homeopathic Drugs** must inform Health & Wellness Product Safety via email at [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) of any customer reports of adverse events or serious adverse events within 48 hours of receiving such report. Suppliers must submit to FDA, on behalf of Walmart and/or Sam’s Club, serious adverse event reports within 15 business days of receipt of the initial complaint. Health & Wellness Product Safety must be copied on all serious adverse event reports submitted to FDA on its behalf as well as all follow-up reports of additional information submitted to FDA on behalf of Walmart and/or Sam’s Club.

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 or via email at [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com).

**Suppliers of Private Brand and Direct Import OTC Homeopathic Drugs are** responsible for investigating product complaints and must provide information regarding the investigative outcome to Health & Wellness Product Safety upon completion.

## Claims

Health-related advertising claims about Health and Wellness Products, which include claims in an online product description, are regulated primarily by the FTC. Statements made about Health and Wellness Products must be truthful and not misleading and must have adequate substantiation by competent and reliable scientific evidence. FTC’s [Health Products Compliance Guidance](#) is a helpful tool for figuring out what kinds of claims and substantiation are appropriate for Health and Wellness Products. Claims about OTC Homeopathic Drugs must be consistent with the use described in the Drug Facts Labeling.

If an OTC Homeopathic Drug supplied to Walmart or Sam’s Club makes an efficacy claim on the package, labeling, or in the online product description, it must be accompanied by a disclaimer that effectively communicates to consumers that: (1) there is no scientific evidence that the product works and (2) the product’s claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts. The disclaimer should stand out and be near the efficacy message; to be effective, it may need to be incorporated into the efficacy message. It should not be undercut or qualified with additional positive statements or consumer endorsements reinforcing the product’s efficacy.

All OTC Homeopathic Drugs supplied for sale at Walmart or Sam's Club must have the word "Homeopathic" on the packaging or labeling.

All OTC Homeopathic Drugs supplied for sale at Walmart or Sam's Club must state the ingredients listed in terms of dilution, e.g., 1X, 6X, 2C.

**Private Brand and Direct Import OTC Homeopathic Drugs** will undergo a claims review by Health & Wellness Product Safety.



# Supplier Requirements for OTC Dietary Supplements

Health & Wellness Product Safety



## Dietary Supplement?

A dietary supplement is a product that contains a "dietary ingredient" - vitamins; minerals; herbs or other botanicals; amino acids; and other substances such as probiotics, enzymes, extracts, or concentrates – that is generally derived from food and intended to supplement the human diet. Dietary supplements must be ingested. They are not topical or injectable products. Dietary supplements usually come in the form of tablets, capsules, soft gels, gel caps, liquids, or powders.

Dietary supplements should not be confused with OTC drugs.

## Do Dietary Supplements Require Approval by FDA?

Dietary supplements are regulated by FDA, but generally do not require FDA approval. FDA regulates the types of ingredients allowed in dietary supplements and the types of claims that can be made about an ingredient and/or a product.

While dietary supplements are not formally “approved” by FDA in the same way that some drugs are, to be legally marketed in the U.S. the dietary ingredient in a dietary supplement must either have been marketed as a dietary ingredient in the U.S. before October 15, 1994, be generally recognized as safe by FDA, been submitted to FDA as a “new dietary ingredient,” or be marketed pursuant to an approved food additive petition.

Dietary supplements also must meet specific labeling requirements. Dietary Supplement labeling must contain the following elements:

- the statement of identity (name of the dietary supplement),
- the net quantity of contents statement (amount of the dietary supplement),
- the nutrition labeling,
- the ingredient list, and
- the name and place of business of the manufacturer, packer, or distributor.

FDA also requires that dietary supplements be manufactured in accordance with FDA’s rules on CGMPs, which set quality requirements and standards throughout the manufacturing, packaging, labeling, and storing of dietary supplement products.

All Suppliers of Dietary Supplements are responsible for ensuring that their products meet the definition of Dietary Supplement in the FD&C Act and are marketed in accordance with FDA’s regulations and guidance. In addition, Suppliers of dietary supplements must ensure that their products are not adulterated or misbranded under the FD&C Act, meaning, for example, that they are labeled appropriately with all required statements and sections and do not contain any ingredients not listed on the label. **Suppliers of Private Brand and Direct Import Dietary Supplements will undergo a full review and verification of all labeling artwork in addition to the requirements set out below.**

# Legal and Regulatory Requirements for Suppliers of OTC Dietary Supplements

## Facility Disclosure and Registration

Suppliers of Dietary Supplements 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 Supplier, but from which Health and Wellness 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 prior to supplying Dietary Supplements produced in that facility.**

All Dietary Supplements sold in the U.S. must be manufactured in facilities registered with FDA. Facility information provided to Health & Wellness Product Safety must match the information on the FDA [Food Facility Registration](#) and must remain accurate. Suppliers must provide FDA registration information to 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](mailto:HWSCSAFETY@wal-mart.com) to obtain the appropriate facility information form.

## State Requirements

Certain states have licensing and registration requirements above and beyond federal registration requirements. All Suppliers of OTC Dietary Supplements are responsible for ensuring compliance with applicable state laws.

Suppliers must submit proof of any state registrations to Health & Wellness Product Safety prior to supplying product as well as when those licenses are renewed. 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.

## Current Good Manufacturing Practices

All Dietary Supplements supplied must be manufactured in facilities that are in good standing with FDA (i.e., not “Official Action Indicated” and no outstanding significant 483s) and manufactured in accordance with CGMPs. 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, if any.

## Third Party Certification and Annual Audit

**National Brand and DSV Suppliers** of Dietary Supplements must provide to Health & Wellness Product Safety a certification of conformance with CGMPs, 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 a Dietary Supplement supplied to Walmart or Sam's Club.

**Private Brand and Direct Import Suppliers of Dietary Supplements** must provide to Health & Wellness Product Safety full reports of third-party cGMP audits showing conformance with CGMPs for each facility involved in the manufacturing process for a Dietary Supplement supplied to Walmart or Sam's Club. Additional social audits may also be required by Walmart's Responsible Sourcing team. The third-party audit firms approved by Walmart are provided in the [Approved Third-party CGMP 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, Supplier will be responsible for providing updated conformance audit and certification documentation to Health & Wellness Product Safety annually. Additionally, CGMP 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](mailto:HWAudits@walmart.com) on or before the anniversary of the preceding audit. You may email [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) should you have any questions regarding CGMP audit and certification conformance.

## Ingredients

All Suppliers are responsible for ensuring that all ingredients in their Dietary Supplements are considered dietary ingredients by FDA. A dietary ingredient contained in a dietary supplement must have been marketed in the U.S. prior to October 15, 1994 (i.e., "grandfathered"), or it will be considered a new dietary ingredient (NDI) and must be either the subject of an NDI notification to FDA or exempt from the notification requirement to FDA under the FD&C Act.

Walmart maintains a list of [prohibited ingredients and prohibited Dietary Supplements](#). It is the responsibility of every Walmart and Sam's Club Supplier to ensure that their products are not on the prohibited products list and do not contain ingredients prohibited by Walmart and Sam's Club. These lists are incorporated by reference into the Supplier Agreement.

**Private Brand and Direct Import Dietary Supplements** will undergo an ingredient review by Health & Wellness Product Safety.

## Labeling

The labeling of dietary supplement products must be consistent with the requirements set out by FDA. A dietary supplement label must:

- Identify the product as a “dietary supplement;”
- Include a “Supplement Facts” box with required nutrient/dietary ingredient declarations;
- Include a list of ingredients;
- Bear a net weight statement;
- Identify the manufacturer, distributor, or packer;
- Bear information for the reporting of adverse events;
- Bear directions for use appropriate to the serving size and warnings as appropriate; and
- Bear allergen labeling where required.

All Suppliers of dietary supplements are responsible for ensuring compliance with these requirements.

All Suppliers must ensure that their products comply with the requirements of the Poison Prevention Packaging Act, including, where applicable, the use of child resistant caps. Suppliers must provide to Health & Wellness Product Safety a current General Certificate of Conformity for each size container of a Dietary Supplement 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. Dietary Supplements are also subject to Country-of-Origin labeling requirements per U.S. Customs and Border Patrol.

**Private Brand and Direct Import Dietary Supplements** will undergo a labeling review by Health & Wellness Product Safety.

## Claims

Health-related advertising claims about Health and Wellness Products, which include claims in an online product description, are regulated primarily by the Federal Trade Commission (FTC). Statements made about Health and Wellness Products must be truthful and not misleading and must have adequate substantiation by competent and reliable scientific evidence. FTC’s [Health Products Compliance Guidance](#) is a helpful tool for figuring out what kinds of claims and substantiation are appropriate for Health and Wellness Products.

## Specific guidance about Dietary Supplement Claims

- Health Claims

Health claims are claims **that characterize a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition**. All health claims that appear on the label or labeling of a dietary supplement must be in compliance with FDA's health claim regulations. A health claim describes the effect a substance has on reducing the risk of or preventing a disease, e.g., "calcium may reduce the risk of osteoporosis." A health claim requires FDA evaluation and authorization prior to its use.

- Nutrient Content Claims

A nutrient content claim is a claim that characterizes **the level of nutrient** in a product. All nutrient content claims that appear on the label or the labeling of a dietary supplement must be in compliance with FDA's nutrient content claim regulations. Nutrient content claims describe the level of a nutrient in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*.

- Statements of Nutritional Support (aka "Structure/Function" Claims)

The following statements may be made for a dietary supplement:

- a claim related to a classical nutrient deficiency disease (like vitamin C and scurvy), but such claims are allowed only if they also say how widespread such a disease is in the United States;
- a claim that describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, for example, "calcium builds strong bones;"
- a claim that characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity;" or
- a claim that describes general well-being from consumption of a nutrient or dietary ingredient. An example of an acceptable claim is "a good diet promotes good health and prevents the onset of disease" or "better dietary and exercise patterns can contribute to disease prevention and better health."

The FDA requires that the following disclaimer be present in connection with all Statements of Nutritional Support on the product labeling or packaging: **"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

These three types of claims are not pre-approved by FDA, but the manufacturer must have substantiation that the claim is truthful and not misleading and must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim. All Suppliers of dietary supplements to be sold by Walmart or Sam's Club must ensure that "notification letters" have been sent to FDA within the required timeframe.

**Private Brand and Direct Import Suppliers of Dietary Supplements** will undergo a claim review by Health & Wellness Product Safety and are required to submit "notification letters" directly to FDA.

### **Adverse Event Reporting**

The manufacturer, packer, or distributor whose name appears on the label of a dietary supplement is responsible for reporting to FDA "serious adverse events," as defined and required under the Dietary Supplement and Nonprescription Consumer Protection Act of 2006, within 15 business days of receipt. All Suppliers of dietary supplements must have SOPs in place or otherwise ensure compliance with federal adverse event reporting requirements.

For dietary supplements, the labeling must reflect the manufacturer's contact information for adverse event reporting. For these products, all adverse event reporting to FDA is done by the Supplier. 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 Dietary Supplements** must inform Health & Wellness Product Safety via email at [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) of any customer reports of adverse events or serious adverse event within 48 hours of receiving such report. Suppliers must <mailto:submit> to FDA, on behalf of Walmart and/or Sam's Club, serious adverse event reports within 15 business days of receipt of the initial complaint. Health & Wellness Product Safety must be copied on all serious adverse event reports submitted to FDA by Private Brand and Direct Import suppliers as well as all follow-up reports of additional information submitted to FDA on behalf of Walmart and/or Sam's Club.

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 or via email at [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com).

**Suppliers of Private Brand and Direct Import Dietary Supplements** are responsible for investigating product complaints and must provide information regarding the investigative outcome to Health & Wellness Product Safety upon completion.



# Supplier Requirements for OTC Medical Devices

Health & Wellness Product Safety

## What is a Medical Device?

Medical devices are regulated in the United States by the FDA and include a wide range of products including hip implants, infusion pumps, ventilators, breast implants, diagnostic tests (pregnancy tests, blood glucose tests, etc.) and relatively simple devices such as tongue depressors, thermometers, and bandages.

Medical Devices sold by Walmart and Sam's Club will generally be considered "consumer medical devices" (i.e., Class I and Class II medical devices). These devices are sold over-the-counter (OTC), which means they are not sold by prescription only or distributed and used exclusively in health care settings. Generally, no training is necessary to use an OTC medical device. Rather, these devices are sufficiently user-friendly for laypersons without training. Manufacturers of OTC medical devices rely on labeling, design, and consumer familiarity to ensure safe and effective use. Most OTC medical devices are not subject to FDA's premarket review requirements but are subject to registration and listing requirements with FDA.

## How are Medical Devices Classified?

Medical devices are assigned one of three classes based on the risks associated with the use of the device. Some lower-risk devices, such as OTC devices, may be exempt from FDA premarket review and notification requirements, but are still subject to FDA registration and listing requirements and may also be subject to FDA's Current Good Manufacturing Practices (CGMP) requirements. The majority of products eligible to be sold by Walmart and Sam's Club are Class I exempt medical devices.

- The database of Class I exempt medical devices is on the FDA's website at [Medical Device Exemptions 510\(k\) and GMP Requirements](#). These items may include general consumer medical devices like bandages, dental floss, and teething rings. There are also a small number of Class II exempt devices.
- A few Class I and Most Class II medical devices must be reviewed by the FDA through a [510\(k\) clearance](#) before they can be made available for sale in the U.S. Many of these devices are cleared for prescription-only use or use only in health care settings.
- Class III medical devices must be approved by the FDA through a [Premarket approval](#) before they can be made available for sale in the U.S. Class III medical devices are highest-risk and are approved for prescription-only use or use only in health care settings.

All medical devices must be manufactured in facilities registered with the FDA and must be listed with FDA ([Establishment Registration & Listing](#)). Even though Class I exempt devices do not require premarket review by the FDA, they still must be listed with the FDA through this process and may still be subject to CGMP requirements.



All Suppliers of Medical Devices must ensure that their products meet all legal and regulatory requirements, including requirements under the Federal Food, Drug and Cosmetic Act (FD&C Act) and FDA's regulations and guidance. Medical Devices that do not follow FDA's regulations, such as by having instructions that do not align with their intended use, or that are not manufactured in an FDA-registered facility may be considered misbranded or adulterated and unlawful to sell in the U.S. **Suppliers of Private Brand and Direct Import Medical Devices will undergo a full review and verification of all labeling artwork in addition to the requirements set out below.**

## Legal and Regulatory Requirements for Suppliers of Medical Devices

### Facility Disclosure and Registration

Suppliers of Medical Devices 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 OTC Medical Devices 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 prior to supplying Medical Devices produced in that facility.**

All Medical Devices sold in the U.S. must be manufactured in facilities registered with FDA. Facility information provided to Health & Wellness Product Safety must match the information on the [Device Registration and Listing website](#) and must remain accurate. Suppliers must provide FDA registration information to 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](mailto:HWSCSAFETY@wal-mart.com) to obtain the appropriate facility information form.

### State Requirements

Certain states have licensing and registration requirements above and beyond federal registration requirements. All Suppliers of OTC Medical Devices are responsible for ensuring compliance with applicable state laws.

Suppliers must submit proof of any state registrations to Health & Wellness Product Safety prior to supplying product as well as when those licenses are renewed. 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.

### Medical Device Listing

All Medical Device Suppliers are required to ensure that their products are appropriately device-listed with FDA.

## Quality System Regulation (QSR)

All Medical Devices supplied must be manufactured in facilities that are in good standing with FDA (i.e., not “Official Action Indicated” and no outstanding significant 483s) and manufactured in accordance with QSRs. 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, if any.

## Third Party Certification and Annual Audit

**National Brand and DSV Suppliers** of Medical Devices must provide to Health & Wellness Product Safety a certification of conformance with QSRs, 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 a Dietary Supplement supplied to Walmart or Sam’s Club.

**Private Brand and Direct Import Suppliers** of Medical Devices must provide to Health & Wellness Product Safety full reports of third-party CGMP audits showing conformance with QSRs for each facility involved in the manufacturing process for a Dietary Supplement supplied to Walmart or Sam’s Club. Additional social audits may also be required by Walmart’s Responsible Sourcing team. The third-party audit firms approved by Walmart are provided in the [Approved Third-party CGMP 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, Supplier will be responsible for providing updated conformance audit and certification documentation to Health & Wellness Product Safety annually. Additionally, CGMP 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](mailto:HWAudits@walmart.com) on or before the anniversary of the preceding audit. You may email [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) should you have any questions regarding CGMP audit and certification conformance.

## Packaging and Labeling

All Medical Device Suppliers must ensure that the product label:

- Bears the established name of the device;
- Bears a declaration of the net quantity of contents;
- Identifies the name and address of the manufacturer, distributor, or packer;
- and
- Provides adequate directions for use.

**Private Brand and Direct Import Medical Devices** will undergo a labeling review by Health & Wellness Product Safety.

## Claims

Health-related advertising claims about Health and Wellness Products, which include claims in an online product description, are regulated primarily by the Federal Trade Commission (FTC). Statements made about Health and Wellness Products must be truthful and not misleading and must have adequate substantiation by competent and reliable scientific evidence. FTC's [Health Products Compliance Guidance](#) is a helpful tool for figuring out what kinds of claims and substantiation are appropriate for Health and Wellness Products. Claims about medical devices must be consistent with the device's intended use per FDA's product codes and classifications.

**Private Brand and Direct Import Medical Devices** will undergo a claims review by Health & Wellness Product Safety.

## Medical Device Reporting

FDA regulations require Medical Device manufacturers to report no later than 30 calendar days after the day they receive or otherwise become aware of information that reasonably suggests that their Medical Device may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

All Suppliers of Medical Devices must have SOPs in place or otherwise ensure compliance with FDA reporting requirements. The labeling must reflect the manufacturer's contact information for event reporting. For Medical Devices, all reporting to FDA is done by the Supplier. 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 Medical Devices** must inform Health & Wellness Product Safety via email at [HWSCSAFETY@wal-mart.com](mailto:HWSCSAFETY@wal-mart.com) of any customer reports of events within 48 hours of receiving such report. Suppliers must submit to FDA, on behalf of Walmart, the required event reports within 30 days of receipt of the initial complaint. Health & Wellness Product Safety must be copied on all reports submitted to FDA on its behalf as well as all follow-up reports of additional information submitted to FDA on behalf of Walmart.

Product complaints that are not required to be reported to FDA, 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](mailto:HWSCSAFETY@wal-mart.com).

**Suppliers of Private Brand and Direct Import Medical Devices** products are responsible for investigating product complaints and must provide information regarding the investigative outcome to Health & Wellness Product Safety upon completion.



# **OTC Product Recalls, Corrections, and Removals**

Health & Wellness Product Safety

## OTC Product Recalls, Corrections, and Removals

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

Product removals are initiated by a supplier or regulatory agency and at their request are executed by the Walmart Corporate Compliance Recall Team. 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@wal-mart.com](mailto:HWRECALLS@wal-mart.com).

### Recalls, Corrections, and Removal Notices

Recalls are due to a Supplier's removal or correction 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. Recall does not include a market withdrawal or a stock recovery. Examples of reasons to recall product include but are not limited to product that does not meet product specification, fails to have required warning, 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 Corporate Compliance Recall Team 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 the Walmart Corporate Compliance Recall Team at [HWRECALLS@wal-mart.com](mailto:HWRECALLS@wal-mart.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 Walmart or Sam's Club 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 or Sam's Club Distribution Centers or Fulfillment 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 handled centrally by the Walmart Corporate Compliance Recall Team. 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](#).**

## Approved Third-Party cGMP Audit and Certification Bodies For Private Brand, Exclusive, and Direct Import Health & Wellness Products

Third-party cGMP conformance audit documents, cGMP Certificates, and Corrective Action Plan (CAP) documents for third-party cGMP audit non-conformances should be emailed to [HWAudits@walmart.com](mailto:HWAudits@walmart.com).

| Product Categories                  | Third Party Audit Program                                                                                                                                                                                                              | Audit Standard |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| OTC Drugs and OTC Homeopathic Drugs | <ul style="list-style-type: none"> <li>UL Retail Certification Program (RCP)</li> <li>NSF OTC GMP Compliance Audit – ANSI 455-4</li> </ul>                                                                                             | 21 CFR 210/211 |
| Dietary Supplements                 | <ul style="list-style-type: none"> <li>Supplement Safety &amp; Compliance Initiative (SSCI) Recognized Certification Bodies</li> <li>UL Retail Certification Program (RCP)<br/><i>(UL-RCP accepted until December 2023)</i></li> </ul> | 21 CFR 111     |
| Sports Nutrition Supplements        | <ul style="list-style-type: none"> <li>NSF Certified for Sport</li> <li>Supplement Safety &amp; Compliance Initiative (SSCI) Recognized Certification Bodies</li> </ul>                                                                | 21 CFR- 111    |
| Medical Devices                     | <ul style="list-style-type: none"> <li>UL Retail Certification Program (RCP)</li> <li>Medical Device Single Audit Program (MDSAP)-<br/>List of Audit Organizations</li> </ul>                                                          | 21 CFR 820     |

# Supplier Checklists by Product Type

## OTC Drugs

| OTC Drug Requirements                     | Private Brand Supplier | Direct Import Supplier | National Brand Supplier | DSV Supplier |
|-------------------------------------------|------------------------|------------------------|-------------------------|--------------|
| Facility Information                      | ✓                      | ✓                      | ✓                       | ✓            |
| FDA Facility Registration                 | ✓                      | ✓                      | ✓                       | ✓            |
| State Licensing                           | ✓                      | ✓                      | ✓                       | ✓            |
| Drug Listing                              | ✓                      | ✓                      | ✓                       | ✓            |
| Certification of Facility CGMP Compliance | ✓                      | ✓                      | ✓                       | ✓            |
| Full Reports of CGMP Audits               | ✓                      | ✓                      |                         |              |
| NDA or ANDA Approval (if applicable)      | ✓                      | ✓                      | ✓                       | ✓            |
| OTC Monograph Certification               | ✓                      | ✓                      | ✓                       | ✓            |
| Labeling Review                           | ✓                      | ✓                      |                         |              |
| Packaging Review                          | ✓                      | ✓                      |                         |              |
| Adverse Event Reporting Process           | ✓                      | ✓                      | ✓                       | ✓            |
| Product Complaint Investigation Process   | ✓                      | ✓                      |                         |              |
| Claim Substantiation                      | ✓                      | ✓                      | ✓                       | ✓            |
| Claim Review                              | ✓                      | ✓                      |                         |              |



## OTC Homeopathic Drugs

| OTC Homeopathic Drug Requirements         | Private Brand Supplier | Direct Import Supplier | National Brand Supplier | DSV Supplier |
|-------------------------------------------|------------------------|------------------------|-------------------------|--------------|
| Facility Information                      | ✓                      | ✓                      | ✓                       | ✓            |
| FDA Facility Registration                 | ✓                      | ✓                      | ✓                       | ✓            |
| State Licensing                           | ✓                      | ✓                      | ✓                       | ✓            |
| Drug Listing                              | ✓                      | ✓                      | ✓                       | ✓            |
| Certification of Facility CGMP Compliance | ✓                      | ✓                      | ✓                       | ✓            |
| Full Reports of CGMP Audits               | ✓                      | ✓                      |                         |              |
| Labeling Review                           | ✓                      | ✓                      |                         |              |
| Packaging Review                          | ✓                      | ✓                      |                         |              |
| Adverse Event Reporting Process           | ✓                      | ✓                      | ✓                       | ✓            |
| Product Complaint Investigation Process   | ✓                      | ✓                      |                         |              |
| Homeopathic Disclaimers                   | ✓                      | ✓                      | ✓                       | ✓            |
| Claim Substantiation                      | ✓                      | ✓                      | ✓                       | ✓            |

## Dietary Supplements

| Dietary Supplement Requirements           | Private Brand Supplier | Direct Import Supplier | National Brand Supplier | DSV Supplier |
|-------------------------------------------|------------------------|------------------------|-------------------------|--------------|
| Facility Information                      | ✓                      | ✓                      | ✓                       | ✓            |
| FDA Facility Registration                 | ✓                      | ✓                      | ✓                       | ✓            |
| State Licensing                           | ✓                      | ✓                      | ✓                       | ✓            |
| Drug Listing                              | ✓                      | ✓                      | ✓                       | ✓            |
| Certification of Facility CGMP Compliance | ✓                      | ✓                      | ✓                       | ✓            |
| Full Reports of CGMP Audits               | ✓                      | ✓                      |                         |              |
| Ingredient Review                         | ✓                      | ✓                      |                         |              |
| Labeling Review                           | ✓                      | ✓                      |                         |              |
| Packaging Review                          | ✓                      | ✓                      |                         |              |
| Adverse Event Reporting Process           | ✓                      | ✓                      | ✓                       | ✓            |
| Product Complaint Investigation Process   | ✓                      | ✓                      |                         |              |
| Claim Notification Letter                 | ✓                      | ✓                      |                         |              |
| Claim Substantiation                      | ✓                      | ✓                      | ✓                       | ✓            |
| Claim Review                              | ✓                      | ✓                      |                         |              |

## Medical Devices

| Medical Device Requirements              | Private Brand Supplier | Direct Import Supplier | National Brand Supplier | DSV Supplier |
|------------------------------------------|------------------------|------------------------|-------------------------|--------------|
| Facility Information                     | ✓                      | ✓                      | ✓                       | ✓            |
| FDA Facility Registration                | ✓                      | ✓                      | ✓                       | ✓            |
| State Licensing                          | ✓                      | ✓                      | ✓                       | ✓            |
| Device Listing                           | ✓                      | ✓                      | ✓                       | ✓            |
| Certification of Facility QSR Compliance | ✓                      | ✓                      | ✓                       | ✓            |
| Full Reports of QSR Audits               | ✓                      | ✓                      |                         |              |
| Labeling Review                          | ✓                      | ✓                      |                         |              |
| Packaging Review                         | ✓                      | ✓                      |                         |              |
| Medical Device Reporting Process         | ✓                      | ✓                      | ✓                       | ✓            |
| Product Complaint Investigation Process  | ✓                      | ✓                      |                         |              |
| Claim Substantiation                     | ✓                      | ✓                      | ✓                       | ✓            |
| Claim Review                             | ✓                      | ✓                      |                         |              |