Supplier Requirements for Over-the-Counter Drugs, Vitamins, and Dietary & Nutritional Supplements.

Providing safe and affordable healthcare products so people can live better.
Purpose

To supply Health & Wellness products to Walmart or Sam’s Club, you are expected to comply with all applicable federal, state, and local regulatory requirements. In addition, the following expectations and criteria must be met. Failure to comply with the requirements in this document could make your company ineligible to supply product to Wal-Mart Stores, Inc., Sam’s Club West, Inc., and its subsidiaries (collectively referred to as Walmart). These requirements are not intended to be all inclusive of your agreement with Walmart, but they do highlight relevant product safety requirements.

Health & Wellness products include all over-the-counter drugs, vitamins, dietary & nutritional supplements, as well as personal care and/or cosmetics containing active pharmaceutical ingredients. If you are unsure if the products you supply are subject to the following requirements, please contact Health & Wellness Product Safety at 479-273-8054 or via email at HWSCSAFETY@wal-mart.com

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Supplier Definitions

At Wal-Mart Stores, Inc., our commitment to our customers is unparalleled. We strive relentlessly to provide safe, quality healthcare products in our retail operations. As part of our commitment to continuous improvement, we require suppliers to demonstrate that they meet or exceed FDA Good Manufacturing Practices & Good Distribution Practices throughout the entire supply chain.
Private Label Suppliers:

Private label suppliers are those suppliers that manufacture, package, or distribute a Walmart or Sam’s Club “private label” product. A Walmart or Sam’s Club private label product is identified by the following criteria:

- Items with a brand name or logo that is owned by Wal-Mart Stores, Inc., Sam’s Club West, or its subsidiaries.

- Items with a brand name or logo that is exclusively licensed to Wal-Mart Stores, Inc. or its subsidiaries by the owner of the brand name or logo.

- Unbranded items labeled as “Distributed by” or “Marketed by” Wal-Mart Stores, Inc. or Sam’s Club West, Inc.

As you are aware, Walmart requires that the products we purchase comply with all laws and safety standards. Walmart does not provide legal advice to its suppliers, so where needed, suppliers should seek their own legal counsel on how to comply with laws applicable to their products.
Private Label Supplier Requirements

(Pages 5-9)
The following expectations and criteria must be met and all information must be provided to the Walmart Home Office Health & Wellness Product Safety team for approval prior to being given an approved supplier agreement. Failure to comply with the requirements listed below may make your company ineligible to supply to Walmart. Please note, these supplier requirements are in addition to Responsible Sourcing Standards for Suppliers and apply to all existing and new suppliers.

Supplier Factory & Facility Disclosure

Facility disclosure is essential to achieving true supply chain transparency. To supply private label products to Walmart, each facility that engages in the manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of private label Health & Wellness products must be disclosed to Health & Wellness Product Safety. This includes all subcontracted facilities or any operations and facilities that are not owned by your company, but from which you may use to source items that are used in the private label products. Once approved as a supplier, you will be responsible for disclosing any new facility and must receive facility approval prior to use. Additionally, you must maintain accurate facility information with Health & Wellness Product Safety. Email Health & Wellness Product Safety at HWSCSAFETY@walmart.com to obtain the appropriate supplier/factory disclosure form.

FDA Registration

Suppliers must ensure that all facilities providing product to Walmart or Sam’s Club have a current and appropriate registration for domestic or foreign facilities with the United States Food & Drug Administration (FDA). Such registrations may include, but are not limited, to the Drug Establishment Registration and Drug Listing Information (DRLS) or FDA Bioterrorism registration. To ensure compliance, suppliers must provide FDA registration information to Walmart Health & Wellness Product Safety prior to supplying product and annually thereafter.
Licensing & Registration

Certain states have licensing and registration requirements above and beyond federal registration requirements. It is the supplier’s responsibility to be familiar with the laws and regulations in every state in which their product will be sold. Suppliers will be asked to submit proof of registration to Health & Wellness Product Safety prior to supplying product as well as upon renewal. 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.

Third Party Certification & Annual Audit

OTC Drugs, Vitamins, Dietary & Nutritional Supplements:

All suppliers providing private label Health & Wellness products are required to provide a third party certification and audit showing conformance with current FDA Good Manufacturing Practices (cGMP) specific for the type of products manufactured, prepared, propagated, compounded, processed, stored, packaged, or labeled in each respective facility or operation. This means that each facility disclosed as outlined under the Factory & Facility Disclosure section must provide cGMP certification and cGMP conformance audit documentation by a Walmart approved third party auditing body annually to Health & Wellness Product Safety. Third party cGMP audits and certifications are in addition to any audits required by Walmart’s Responsible Sourcing team.

Approved Third Party Audit Firms:

Please review the Approved Third-party cGMP Audit Information* to ensure your current audit company is approved by Walmart to conduct audits for the products you produce. If you have never had a third party cGMP audit, please review the Approved Third-party cGMP Audit Information* for a list of approved audit companies that can conduct an audit at your facility.
Audits must have been conducted within the current 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 in order to receive approval. Additional conformance audits may be required. Once approved, the 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 on or before the anniversary of the proceeding audit. You may email HWSCSAFETY@wal-mart.com should you have any questions regarding cGMP audit and certification conformance.
Third Party Certification & Annual Audit (cont.) -

**Diet & nutrition, meal replacements, & other food items:**

Walmart Stores, Inc. has aligned with GFSI (Global Food Safety Initiative) and requires all private brand suppliers providing food items, including food items typically merchandised in the Over-the-Counter sales areas, to obtain full GFSI certification. GFSI is required for Walmart private label food suppliers regardless of company size or the inherent food safety risks associated with their products. For more information about the certification process, you may review The Supplier’s Guide to Becoming GFSI Certified*. Please visit [www.mygfsi.com](http://www.mygfsi.com) for a full list of recognized schemes.

Once approved by Health & Wellness Product Safety, the supplier will be responsible for providing updated GFSI certification to Health & Wellness Product Safety annually on or before certification expiration.

You may email HWSCSAFETY@wal-mart.com should you have any questions regarding third party certification and annual audit compliance.
Product Removal Requirements

(Pages 10-12)
Product Removal Requirements

At Walmart, we adhere to strict quality assurance controls and work with our supplier partners 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 Food Safety & Health Recall Team. In some cases however, a recall or withdrawal may be initiated by Walmart due to internal information (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 Food Safety & Health Recall Team at 479-644-9606 or FOODRECA7@wal-mart.com.

Product removals are classified under two categories:

• Recall - safety-related product removals: 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.

• Withdrawal - non-safety-related product removals: Reasons to withdraw products include but are not limited to product or package appearance. These products are perfectly safe to consume or use, but do not meet a non-safety related regulation or the supplier’s desired quality.
Product Removals Continued:

If a product removal is necessary for one of your products or if you have any concerns with the safety of your product, please immediately contact the Walmart Food Safety & Health Recall Team at 479-644-9606 or FOODRECA7@walmart.com. You will be directed to either complete a product removal form via your supplier access to Retail Link, or if you do not have access to Retail Link, contact the Food Safety & Health Recall Team.

Help us help you! If you need to contact the Recall Team, please have the following information ready to provide the team:

- 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
- DC facility list that received the implicated product
- Disposition and handling instructions of the product,
- Press Release: Will there be a press release regarding the recall?
Product Complaints

(Pages 13-14)
**Complaints**

Product complaints may be received from customers either directly to the supplier or by other means. Suppliers must immediately report customer complaints of adverse events, serious adverse events, foreign objects, or tampering to Health & Wellness Product Safety at 479-273-8054 or via email at HWSCSAFETY@wal-mart.com.

Suppliers of private label Health & Wellness products are responsible for investigating product incidents and must provide information regarding the investigative outcome to Health & Wellness Product Safety upon completion. Additionally, private label suppliers must submit on behalf of Walmart required adverse event reports for dietary supplements and nonprescription drugs in accordance with 21 U.S. Code 379aa (b)(2). Such reports are to be submitted to the FDA within 15 business days upon receipt of the initial complaint. Health & Wellness Product Safety must also be copied on all adverse event reports as well as all follow-up reports or new medical information submitted to the FDA on behalf of Walmart.
Packaging and Labeling Requirements

(Pages 15-16)
It is the supplier’s responsibility to understand and comply with all federal, state, and local regulatory requirements for packaging and labeling.

**Packaging**

Packaging requirements include, but are not limited to, complying with Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Dietary Supplement Products as well as child-resistant cap certificates as required under Section 14(a)(2) of the Consumer Product Safety Act (CPSA) and 21 CFR Part 1700.

Private brand suppliers must provide to Health & Wellness Product Safety a current General Certificate of Conformity for each size container of over-the-counter medication or 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.

**Labeling**

Private label suppliers are responsible for all federal, state, and local regulatory labeling requirements. Such requirements include, but are not limited to, DSHEA labeling requirements, FDA labeling requirements for pharmaceuticals and dietary supplements, Food Allergen Labeling Act, Fair Packaging and Labeling Act, and country of origin labeling under the U.S. Tariff Act. Additionally, private label suppliers are responsible for demonstrating claim substantiation on behalf of Walmart or Sam’s private label products. Finally, private label suppliers will be responsible for any costs associated with conducting third party regulatory
Appendix

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Approved Third Party cGMP Audit and Certification

Recognized Third-Party Audits and Certifications

Please note that any audits from audit firms not listed below must be submitted to Health & Wellness Product Safety for consideration and approval. Each facility must have a third party cGMP audit and certification demonstrating conformance to applicable FDA Good Manufacturing Requirements.

<table>
<thead>
<tr>
<th>Product Categories</th>
<th>Third Party Audit Program</th>
<th>Audit Standard</th>
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<tbody>
<tr>
<td>OTC Pharmaceuticals</td>
<td>UL Retail Certification Program (RCP)</td>
<td>21 CFR 210/211</td>
</tr>
<tr>
<td></td>
<td>NSF OTC GMP Compliance Audit</td>
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<tr>
<td>Dietary Supplements</td>
<td>UL Retail Certification Program (RCP)</td>
<td>21 CFR 111</td>
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<tr>
<td></td>
<td>NSF Dietary Supplement GMP Registration/Certification Audit</td>
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<tr>
<td></td>
<td>USP Verified Dietary Supplement Program</td>
<td></td>
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<tr>
<td>Sports Nutrition Supplements</td>
<td>NSF Certified for Sport ®</td>
<td>21 CFR 111</td>
</tr>
</tbody>
</table>
The Supplier’s Guide to Becoming GFSI Certified

Please note that the time needed to prepare for a GFSI certification assessment will vary between companies. The complete process, from choosing a scheme through final assessment, may take between 6-12 months.

**Step 1 - Choose a Scheme**

Review the GFSI recognized schemes to determine which best fits your company and the programs currently implemented. Each scheme is linked to the standard owner’s website. Here you can learn more about their certification processes and requirements. Please note that the Manufacturing Schemes are for processors while the Primary Production Schemes are for produce suppliers.

**Step 2 - Understand the Requirements**

Request or download a copy of the scheme's standard. The standard includes all of the requirements against which your facility will be assessed. Standards may be ordered or downloaded by visiting the standard owner's website or by contacting the standard owner. Depending on the scheme you select, the cost for the standard could range from $0-$200. Many of the standard owner's offer training courses over their schemes and, although usually not required, these courses may be attended to better understand the requirements. For more information and cost of these training courses, please visit the standard owner’s website.

**Step 3 - Prepare for the Audit**

To begin your preparation, it is suggested that your facility perform a gap analysis. A gap analysis is where you assess your facility against the standard’s requirements to identify the areas where you do not meet the requirements or where you have gaps. If your company is familiar with the expectations of the scheme, you may conduct this assessment yourself. If you do not feel comfortable conducting the gap analysis yourself, your company may also hire someone from an approved certification body to perform the gap analysis. Please note that the certification body you use to perform a gap analysis cannot be the same certification body used to perform your final GFSI certification assessment. For more information on certification bodies, please see Step 4.

**Step 4 - Choose a Certification Body & Schedule the Assessment**

Certification bodies must demonstrate their knowledge in a scheme and be approved to conduct assessments. This means you must ensure you choose a certification body that is approved to audit against the scheme you have chosen to be certified against.

You may find a list of approved certification bodies at the standard owner’s website. Please be advised that due to current GFSI certification demand, certification bodies may be fully booked for two to four months and will not be immediately available to conduct your assessment. Because of this, we recommend that you look at your certification timeline and schedule your assessment a few months before you will be ready for your assessment to be conducted.

**Step 5 - Share GFSI Certification with Walmart**

Once you obtain your GFSI certification, you will need to send a copy directly to Health & Wellness Product Safety at HWSCSAFETY@wal-mart.com