



Prescription Product Supplier Requirements

Prescription Product Suppliers:

Prescription product suppliers are those suppliers that manufacture, package, or distribute a prescription pharmaceutical (drug) or other product that requires a legitimate medical prescription to be dispensed by a licensed healthcare professional.

These products are in contrast to over-the-counter products which can be obtained without a prescription.

Such suppliers include, but are not limited to, direct-ship pharmaceutical or device manufacturers, brokers, wholesale drug or device distributors, pharmaceutical & medical device manufacturers, labelers, repackagers, third-party logistic providers (3PL), or any entity arranging for the purchase of prescription pharmaceuticals or devices by Walmart.



Walmart Pharmacy Distribution Network

Prescription product supplier on-boarding is required for all suppliers providing prescription pharmaceuticals or devices directly or indirectly to any of Walmart's Pharmacy Distribution Centers. This includes, but is not limited to, product that is purchased directly or indirectly from a manufacturer or from a third-party wholesale distributor. All information must be provided to Health & Wellness Product Safety for review and approval prior to placing any purchase orders and shipping product. Failure to comply with the following requirements 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 current and new suppliers.



New Supplier Approval

In order to ship product into any of Walmart's Pharmacy Distribution Centers, the supplier must meet or exceed all applicable Federal, State, and local laws and regulatory requirements as well as adhere to any additional requirements stated in the supplier agreement. Additionally, new suppliers must provide requested information to Health & Wellness Product Safety regarding the manufacture and handling of prescription pharmaceuticals and devices. You may contact Health & Wellness Product Safety at HWPSAFE@email.wal-mart.com to obtain the appropriate supplier facility/product disclosure form. Information required shall include, but may not be limited to:

- **Facility Disclosure:** Facility disclosure is essential to achieving true supply chain transparency. Each facility that engages in the manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of the sourced product must be disclosed to Health & Wellness Product Safety. This includes all subcontracted facilities or any operations or facilities that are not owned by your company which provide manufacturing, packaging, labeling, storage, distribution, or logistical services.
- United States Food & Drug Administration (**FDA**) **Drug Establishment Registration or Medical Device Manufacturing Registration** for applicable facilities;
- Applicable **Drug Enforcement Agency (DEA) registration;**
- **Facility Ownership/business relationship:** Facility ownership/business entity relationship disclosure is essential for verification of required licenses;
- **State Board of Pharmacy Wholesale Drug Distributor** license/registration information for the state in which the applicable facility(s) operate as well as for AR, CA, GA, IN, and MD;
- Authorized Distributor of Record (ADR) status information if applicable;

New Supplier Approval Continued:

- **New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)** approval information;
- National Drug Code (**NDC**) registration information;
- 24 month **recall history** for sourced product;
- Facility regulatory enforcement/inspection history information;
- DEA schedule classification applicable to controlled substances;
- VAWD accreditation.



Health & Wellness Product Safety will review all supplier/product information and verify applicable licenses and registrations directly with the issuing State and/or Federal agencies. Once verified and approved, the supplier is responsible for disclosing new facility information prior to use of the new facility as well as maintaining accurate facility and registration information with Health & Wellness Product Safety. As always, it is the supplier's responsibility to renew and maintain all required licenses and registrations with the issuing agencies and provide renewal information to Health & Wellness Product Safety immediately upon renewal. Failure to maintain a required license or registration may make your company ineligible to supply to Walmart.

Suppliers must also confidentially provide electronic transaction information, transaction history and transaction statements (Transactional Data) to Walmart's **RXDSCSA Repository** as such Transactional Data is required to be maintained by Walmart for Drug Supply Chain Security Act eligible product as a "dispenser" pursuant to 21 U.S.C. § 360eee-1(d). Transactional data shall be electronically shared immediately upon shipping of product.

New Product Approval

Before a current supplier can ship a newly sourced product into any of Walmart's Pharmacy Distribution Centers, the supplier must provide the following information to Health & Wellness Product Safety for review and approval. You may contact Health & Wellness Product Safety at HWPSAFE@email.wal-mart.com to obtain the appropriate supplier facility/product disclosure form. Information required shall include, but may not be limited to:



- **Facility Disclosure:** Each facility that engages in the manufacture, preparation, propagation, compounding, processing, packaging, labeling, storage, and distribution of the sourced product must be disclosed to Health & Wellness Product Safety. This includes all subcontracted facilities or any operations or facilities that are not owned by your company which provide manufacturing, packaging, labeling, storage, distribution, or logistical services.
- United States Food & Drug Administration (**FDA**) **Drug Establishment Registration or Medical Device Manufacturing Registration** for applicable facilities;
- Applicable **Drug Enforcement Agency (DEA) registration;**
- **Facility Ownership/business relationship:** Facility ownership/business entity relationship disclosure is essential for verification of required licenses;
- **State Board of Pharmacy Wholesale Drug Distributor** license information for the State in which the applicable facility(s) operate as well as for AR, CA, GA, IN, and MD;
- Authorized Distributor of Record (ADR) status information if applicable;

New Product Approval Continued:

- **New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)** approval information;
- National Drug Code (**NDC**) registration information;
- 24 month **recall history** for sourced product;
- Facility regulatory enforcement/inspection history information;
- DEA schedule classification applicable to controlled substances;
- VAWD accreditation.

Health & Wellness Product Safety will review all supplier/product information and verify applicable licenses and registrations directly with the issuing State and/or Federal agencies. Once verified and approved, the supplier is responsible for disclosing new facility information prior to use of the new facility as well as maintaining accurate facility and registration information with Health & Wellness Product Safety. As always, it is the supplier's responsibility to renew and maintain all required licenses and registrations with the issuing agencies and provide renewal information to Health & Wellness Product Safety immediately upon renewal. Failure to maintain a required license or registration may make your company ineligible to supply to Walmart.

Suppliers must also confidentially provide electronic transaction information, transaction history and transaction statements (Transactional Data) to Walmart's **RXDSCSA Repository** as such Transactional Data is required to be maintained by Walmart for Drug Supply Chain Security Act eligible product as a "dispenser" pursuant to 21 U.S.C. § 360eee-1(d). Transactional data shall be electronically shared immediately upon shipping of product.



Direct-to-Store Wholesale Drug Distributors

Direct-to-Store Wholesale Distributors are full-line wholesalers who purchase, inventory, sell and deliver prescription products to the pharmacy retail level.

In order for such wholesale drug distributors to supply prescription products to Walmart Pharmacies or Sam's Club Pharmacies; the distributor must meet or exceed all applicable Federal, State, and local laws and regulatory requirements as well as adhere to any additional requirements stated in an approved supplier agreement.

Additionally, such distributors are responsible for establishing, maintaining, and enforcing policies and procedures that:

- Ensure the integrity, legitimacy, and authenticity of prescription drug and device purchase orders and deliveries;
- Ensure their suppliers are engaged in the lawful distribution of prescription drugs and devices obtained from legitimate sources;
- Ensure verification of vendor and customer licenses using data from appropriate state and federal agencies, at least annually;
- Ensure all facilities engaged in interstate distribution of prescription products are licensed by the applicable state licensing board as well as hold appropriate DEA registrations; and
- Meet FDA annual prescription drug wholesale distributor reporting requirements.

Finally, such suppliers must also confidentially provide electronic transaction information, transaction history and transaction statements (Transactional Data) to Walmart's **RXDSCSA Repository** as such Transactional Data is required to be maintained by Walmart for Drug Supply Chain Security Act eligible product as a "dispenser" pursuant to 21 U.S.C. § 360eee-1(d). Transactional data shall be electronically shared immediately upon shipping of product.

Product Removal Requirements for Prescription Products

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, you must **immediately** contact the Walmart Food Safety & Health Recall team at **479-644-9606 or FOODRECA7@wal-mart.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.

Please have the following information ready to provide to the Recall 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?

The Food Safety & Health Recall team will promptly notify all impacted facilities using the information that you have provided. **Do not directly notify any Walmart Pharmacy or Sam's Club Pharmacy.** All product removal notifications are handled centrally by Walmart's Home Office Food Safety & Health Recall team.

