



DIRECT IMPORT GUIDE FOR PRODUCT SUPPLIERS

Version Date : July 7, 2021

This Import Guide and additional import information is posted at :

<https://cvssuppliers.com/import-suppliers>

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CVS IMPORT/QA DEPARTMENT CONTACT LIST

Name/Title	Phone (401) 770 & ext. below	E-mail Address	Contact for:
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CVS CONSOLIDATION TERMS AND SHIPMENT WINDOW

CONSOLIDATION

Yusen Logistics is CVS' designated Freight Forwarder / Logistics Provider for all origin points and performs the following:

- Receives all cargo according to CVS Purchase Order specifications
- Verify required export and import documents
- Issue all Forwarders Cargo Receipts (FCR)
- Arrange for all Ocean Bills of Lading
- CVS requires that all cargo be delivered at the supplier's expense to the consolidation point as specified in the Open Account Transaction and consolidated by Yusen Logistics. A complete list of Yusen FOB consolidation points and contacts are listed on page 11. Shipment booking should be placed with Yusen Logistics through its e-booking system and must be made at least 14 days prior to Early Ship Date. For the registration form and e-booking procedure, please go to Yusen Logistics e-booking web-site: <http://griffin3.hk.yusen-logistics.com/ebooking>

FACTORY LOAD

- Factory load requests must be for product with the same destination (e.g., La Habra, Patterson, Kearny, Port Wentworth, Suffolk, Rancho Dominguez and Honolulu).
- Purchase orders for the following DCs may be combined, as all are destined to Rancho Dominguez, CA: Kansas City, MO, Indianapolis IN, Novi MI, Ennis TX, and Conroe/Houston TX.
- Purchase orders for the following DCs may be combined, as all are destined to Port Wentworth, GA: Orlando FL, Bessemer AL, North Augusta/Beech Island SC and Vero Beach FL.
- Purchase orders for the following DCs may be combined, as all are destined to Kearny, NJ: Woonsocket/North Smithfield RI, Lumberton NJ and Chemung/Waverly NY.
- Purchase orders for the following DCs may be combined, as all are destined to Suffolk, VA: Knoxville TN, Somerset, PA and Fredericksburg VA
- If a supplier is unable to fulfill the below equipment criteria, then the freight must be delivered to Yusen for consolidation. Exceptions to this policy must be routed through the CVS Import Department.

EQUIPMENT TYPE	MINIMUM CBM	DESIRED CBM	MAXIMUM WEIGHT
45' High Cube Container	76	77	42,500 pounds
40' High Cube Container	67	68	43,000 pounds
40' Standard Container	58	59	43,000 pounds

CVS SHIPMENT WINDOW

The CVS Purchase Order and Open Account Transaction specify the parameters of CVS product shipment window. Adherence to the pre-defined shipment window is critical to our mutual success. Acceptance of a purchase order means acceptance of the ship window. Shipment is considered delivered when goods and clean documents are accepted as reflected by the FCR transaction date. **The CVS one-week import shipment window is defined as below:**

FIELD	DEFINITION	TIMING	ACTION
ESD	<u>Early Ship Date</u>	Day 1 of 7	First day cargo and documentation may be delivered
FDD	<u>Factory Delivery Date</u>	Day 4 of 7	Preferred date of cargo and documentation delivery
LSD	<u>Last Ship Date</u>	Day 7 of 7	Last date cargo and documentation must be delivered to avoid penalty

FCR PENALTY CLAUSE

Shipments with FCR Transaction Dates past the Last Ship Date will be subject to the below penalties:

FCR COMPLETION DATE	PENALTY LEVEL
1-7 Days after Last Ship Date	1 % Penalty deduction from the Open Account Transaction
8-14 Days after Last Ship Date	2 % Penalty deduction from the Open Account Transaction
15-21 Days after Last Ship Date	3 % Penalty deduction from the Open Account Transaction

CUSTOMS & COMMERCIAL DOCUMENT REQUIREMENTS

UNDERSTANDING CUSTOMS & BORDER PROTECTION (CBP) REQUIREMENTS

CVS Pharmacy Inc. has a legal obligation to provide accurate and complete documentation to Customs and Border Protection (CBP), among other partnering government agencies for its imported merchandise.

Customs published an informal compliance publication to assist importers and shippers understand the requirements and responsibilities involved in the importation process. It is titled, "What Every Member of the Trade Community Should Know About: Reasonable Care (A Checklist for Compliance)" and can be found at the below link: (may be necessary to copy and paste link): <https://www.cbp.gov/document/publications/reasonable-care>

COMMERCIAL DOCUMENT REQUIREMENTS

The accuracy and completeness of information contained on a commercial invoice and packing list are imperative to meet the Reasonable Care guidelines and legal obligations. The supplier is responsible for generating accurate and compliant commercial documents. Below is an adapted summary of the general invoice requirements for CBP purposes, as well as other CVS specific requirements. A copy of the actual Customs Regulation (19 CFR 141.86) can be found at the below link (may be necessary to copy and paste links):

http://edocket.access.gpo.gov/cfr_2004/aprqttr/pdf/19cfr141.86.pdf

Customs Requirements

Seller name and address	Purchasers name and address
Actual manufacturer's name and address	Port of Entry
Country of Origin	Carton marks and numbers
Detailed description of the merchandise	Itemization of values
Purchase price in U.S. dollars	Quantities in weights and measures
Terms of sale	
Assists or extraneous payments to acquire the merchandise	
Discounts or adjustments to the price after purchase order generation	

CVS Additional Requirements

One commercial invoice per supplier	Notify party of the B/L should be:
Delineate all items and purchase orders	Geodis
Open Account Transaction Number	5024 Campbell Blvd. Suite E
General Conformity Certificate (GCC) by item	Baltimore, MD 21236

DUTY ASSESSMENT COMPLIANCE

CVS holds the supplier responsible to submit accurate product duty rates and corresponding HTS numbers. Inaccurate duty rates / HTS numbers that result in a higher duty payment may result in a request for a reduction of the FOB or a supplier charge-back for the difference between actual duty **rate paid verses** the supplier quoted duty rate.

QUANTITY OF MERCHANDISE RECEIVED - OVERAGES

If CVS receives a quantity of merchandise greater than the quantity ordered pursuant to 19 U.S.C. § 1499(a)(3) and 19 C.F.R. §141.4 and that merchandise was not specified on the seller's invoice or included on the U.S. Customs entry, CVS has an obligation to declare the additional merchandise, file the appropriate revised entry documents for the overage and pay the additional duties, fees, and taxes thereon to CBP accordingly. CVS will not reimburse any payment to our suppliers for erroneous overages.

PRODUCT & CARTON MARKINGS

COUNTRY OF ORIGIN MARKING

Federal Regulations mandate that every article imported into the United States must be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article will permit in such a manner as to indicate to the ultimate purchaser in the United States the English name of the articles country of origin.

CARTON SIZE

Cartons must comply with the below size/weight requirement unless approved by the Import Department.

MINIMUM CASE DIMENSIONS	MAXIMUM CASE DIMENSIONS
3" H x 8" W x 8" L – (.11 Cubic Feet)	28" H x 20" W x 30" L – (9.7 Cubic Feet)
Minimum Case Weight = 3 pounds	Maximum Case Weight = 50 pounds

OUTER CARTON MARKINGS

Outer carton must be marked with the CVS item number found on the purchase order, item description, event, po case pack and the origin information. All **seasonal merchandise** requires a **color label eight inches long by five inches wide, printed directly on all four sides of a carton (containing event code, event category and store set up date, as shown in the EDI "PO Comments" field)** or as large as possible for smaller cartons.

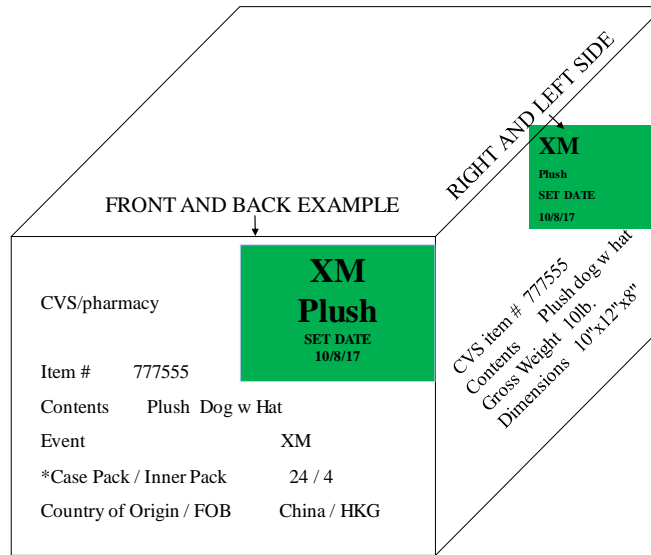
SEASON (EVENT) ****	LETTERING for ODD numbered years	LETTERING for EVEN numbered years	Store Set Up Date	LABEL COLOR - PMS #
Valentine	VA	VA	1/3/2022	Pink - PMS #232
Jan PGM	GP	GJ	1/3/2022	No Fill
Spring / Lawn & Garden	SP	LG	2/16/2022	Yellow - PMS Process Yellow
Easter	EA	EA	2/16/2022	Yellow - PMS Process Yellow
Summer	SM	SU	2/16/22 3/21/22 4/19/22	Blue - PMS #2935
Back to School	BS	BT	5/30/22 7/11/22 7/25/22	Orange -PMS #021
Fall Décor / Thanksgiving	TK	FD	8/15/2022	Brown - PMS #463
Halloween	HA	HW	9/5/2022	Black - PMS Process Black
Fall and Winter	FL	FW	9/5/21 10/3/21 12/1/21	No Fill
Christmas Toys, PGM, Plush, Books & Accessories	XM	XC	9/6/21 10/3/21 11/1/21	Green - PMS #7482
Christmas	XM	XC	11/1/2021	Red - PMS #199
Christmas - Wrap, Boxes, Bows, Ribbon, Bags	XM	XC	11/7/21 11/21/21 12/1/21	Red - PMS #199

**** All seasonal events are not listed. For seasonal events not listed - label color is "No Fill".

Events shown above may have more set dates than noted, review the EDI "po comment" field for correct event code, event category and set date per order. **NOTE:** If you currently do not receive the po comment from your EDI provider - you must contact them to fulfill this requirement.

CARTON MARKING EXAMPLES

Sample carton markings for all DCs:



***Note: Displays** are to be noted as case pack "1" (no inner pack mark) as reflected on the EDI purchase order. Outer carton of **display merchandise** must be marked with the CVS display number found on the purchase order, not the CVS content numbers.
If there is no inner just list "case pack".

INNER PACK AND MASTER PACK MARKINGS

Mark the CVS six-digit item number and number of pieces on inner package and include the event marking as shown on the outer carton.



VERIFICATION

Prior to issuance of a Forwarders Cargo Receipt, Yusen will verify the application and accuracy of carton markings in accordance with the published standard and the specific CVS Purchase Order.

CORRUGATE PACKAGING AND PALLET REQUIREMENTS

Minimum standards for corrugate quality for cartons entering the CVS supply chain must be followed. Understanding that cartons are handled many times by numerous parties on their journey to our stores, it is our goal to insure the product inside the carton arrives in pristine, saleable condition.

While we reference specific requirements below, it is important to understand that CVS does not intend to implement QA testing of corrugate at this point in time. We do intend to work closely with our suppliers, global forwarder, distribution centers and stores to insure corrugate quality is consistent with our expectations. Should corrugate quality fail to meet expectations, CVS reserves the right to have the supplier submit future shipments for QA testing, and / or impose a penalty.

PACKAGING AND PALLET REQUIREMENTS

- Must be designed and structured to ensure the following:
 - Overseas shipping
 - Long haul transportation from port to DC
 - Structural integrity of stacked pallet not to be adversely effected by elevated temperature and/or high relative humidity (greater than 75%)
 - If weight loaded it must be able to withstand 90 days without failure
- Stacking pallets require the following (though shipments are floor loaded in ocean containers -goods are palletized at transload and distribution centers for movement throughout the U.S. to CVS stores)
 - Pallets with loads under or at 750lbs must be able to demonstrate structure by withstanding 1500lbs of weight on the bottom product layer without damage
 - Pallets with loads over 750lbs must be able to demonstrate structure by withstanding 2500lbs of weight on the bottom product layer without damage
 - No overhanging of boxes as these can create stress areas and become subject to load failure
 - Pallet layers must stack flat; product cannot bow in the center of the carton after being taped shut
- Master Shipping Containers
 - Moisture Resistant Adhesive(MRA) must be employed on all corrugate subjected to +75%RH during transit

It is the supplier's responsibility for structural quality/integrity while their product is in the CVS supply chain.

INVOICE AND PACKING LIST

Yusen Logistics web applications for invoice and packing list generation are to be utilized for all shipments.

CVS ITEM PRESENTATION

Genesis Global Sourcing is the Asia sourcing representative exclusive to CVS.

All Direct Import suppliers and factories must complete the Genesis Pre Qualification Process before submitting Import quotations to CVS. Compliance is mandatory in order to become an import supplier for CVS.

Information regarding this process including required documentation may be obtained by contacting Genesis at:
CVSInformation@genesishk.com

All direct import quotations are submitted through Genesis Hong Kong using an on-line portal. The Genesis team will submit the New Item Forms to CVS. Import suppliers should not submit New Item Forms directly to CVS.

Any supplier updates or revisions to Import quotes will be routed through the Genesis team in Asia.

Genesis US Contact

Thomas Logan

Vice President - CVS Operations

Thomas.Logan2@cvscaremark.com

Genesis Hong Kong Contact

Eunice Sum

Assistant General Manager - Merchandising

Eunice@genesishk.com

CVS DIRECT IMPORT PAYMENT PROCESS

All direct import shipments are paid via Open Account Transactions (OATs) managed by The Bank of New York Mellon on behalf of CVS. All pertinent documents stipulated on OATs must be forwarded to BNY Mellon. Invoices should not be submitted to CVS via EDI transmission, nor mailed directly to CVS.

Current terms for Open Accounts are sight + 60 days. (Sight is defined as the day documents are received by BNY Mellon and deemed accurate and complete for payment.)

New suppliers are required to submit an Open Account Vendor Profile to CVS including primary and secondary contacts and banking information, prior to purchase order release - **to the CVS category manager. New suppliers that need to provide a profile for set up on Open Account, please forward to the CVS category manager with a cc to Denise Ehnes at:**
Denise.Ehnes@cvshealth.com and Elaine Lamoureux at Elaine.Lamoureux@cvshealth.com

Subsequent OAT detail, instructions, and remittance advices will be e-mailed by BNY Mellon to the contacts listed on this form. Contacts listed in the Vendor Profile are the only parties that will be forwarded this information. The information listed on the cover letter submitted for presentations must mirror the information provided on the Vendor Form exactly, to avoid payment delays.

Suppliers with general questions about the CVS Open Account program can contact BNY Mellon using the email address:
OATPROCESSING@BNYMELLON.COM

Note: BNY Mellon's pricing for processing open account transactions will be a flat fee plus courier fee for a maximum 20 POs per drawing/presentation, while each additional PO on top of the 20 POs will be charged at a per PO cost. BNY will provide actual costs. A single drawing can comprise any number of document sets (invoices, packing lists, etc.), as long as those sets are accompanied by 1 cover letter indicating 1 OAT Reference No.

i.e. Sets of documents (FCRs, invoices, packing lists) may be presented for up to 20 purchases orders under one cover letter. Of course, document sets may be presented one or two PO's at a time, however full charges apply for each presentation.

MISQUOTATION OF CASE CUBE ON CVS NEW ITEM FORMS

OVERSTATING CARTON DIMENSIONS

- Actual case cube is overstated (New Item Form Height x Width x Length is greater than actual shipped product Height x Width x Length)
- Item actual landed cost is less than estimated by supplier on quote sheet – (actual ocean freight less than ocean freight portion of Import New Item Sheet)
- Actual margin is greater than book margin – excess margin booked to purchase price variance – company numbers reflect accurate margin, margin by CM understated
- Case cube is used by CVS for several reasons: forecasting ocean equipment needs, forecasting space and manpower needs for the DCs, which all have a direct impact on ocean freight costs and shipment lead time

SOLUTION – Suppliers will be charged \$500 USD per item shipment where the cube is incorrectly overstated on the new item form submitted to the Category Manager and used to create purchase orders. CVS will allow a range of up to 10% off before the penalty is enforced. Penalties will be per item shipment. CVS reserves the right to take additional steps, for repeat offenders.

For example: Supplier A submits an item with a case cube of 2 cubic feet, but item actually is 1.9 cubic feet - supplier will not be penalized (5% variance). Supplier B submits an item with a case cube of 2 cubic feet, but item is actually 1.5 cubic feet (25% variance) - supplier will be penalized \$500 USD.

Penalties assessed must be paid within 30 days.

UNDERSTATING CARTON DIMENSIONS

- Actual case cube is understated (New Item Form Height x Width x Length is less than actual shipped product Height x Width x Length)
- Items actual landed cost is more expensive than estimated by supplier on new item form – (actual ocean freight more expensive than ocean freight portion of Import New Item Form). This may make supplier A's price look like a better deal than supplier B's, until you see at a later date the actual landed cost of supplier A's item was greater than supplier B's, who quoted an accurate case cube for his item.
- Actual margin is less than book margin – margin shortfall booked to purchase price variance – company numbers reflect accurate margin, margin by CM overstated
- Case cube is used by CVS for several reasons: forecasting ocean equipment needs, forecasting space and manpower needs for the DCs, which all have a direct impact on ocean freight costs and shipment lead time

SOLUTION – Suppliers will be charged \$500 USD per item where the cube is incorrectly understated on the new item form submitted to the Category Manager and used to create purchase orders. CVS will allow a range of up to 10% before the penalty is enforced. Additionally, the supplier will be charged for any incremental ocean freight charges CVS incurs above what it should have incurred if the carton dimensions were quoted accurately. Penalties will be per item shipment. CVS reserves the right to take additional steps, for repeat offenders.

Penalties assessed must be paid within 30 days.

YUSEN LOGISTICS CONTACT LIST

Duty	Contact	Title	Telephone Number	E-mail
Account Executive - all origins				
Account Executive - all origins	Debbie Wong	Assistant Manager	852-31290282	debbie.wong@hk.yusen-logistics.com
Operation	Yee Kong	Supervisor	852-31290290	yeekong@hk.yusen-logistics.com
Operation	Erica Kwok	Supervisor	852-31290243	erica.kwok@hk.yusen-logistics.com
Operation - HK	Vizo Wong	Coordinator	852-31290277	vizo.wong@hk.yusen-logistics.com
Account Executive - Shenzhen	Samuel Ng	Manager	86-755-32990200	samuel.ng@hk.yusen-logistics.com
Account Executive - Shenzhen	Carol Yang	Senior Supervisor	86-755-32990160	carol.yang@hk.yusen-logistics.com
Account leader - Shenzhen	Gabriela Xie	Senior Coordinator	86-755-32990183	gabriela.xie@hk.yusen-logistics.com
Operation - Shenzhen	Zarina Zheng	Coordinator	86-755-32990150	zarina.zheng@hk.yusen-logistics.com
Operation - Shenzhen	Autumn Lin	Coordinator	86-755-32990166	autumn.lin@hk.yusen-logistics.com
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Documentation - Shenzhen	Alan Xu	Clerk	86-755-32990182	alan.xu@hk.yusen-logistics.com
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Operation - Shanghai	Marie Yao	Coordinator	86-21-22207185	marie.yao@cn.yusen-logistics.com
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Documentation - Shanghai	CVS GROUP			YLCN_CVS_SHA@cn.yusen-logistics.com
Operation - Qingdao	Jessica Zhao	Assistant Manager	86-532-85029715	jessica_zhao@cn.nyklogistics.com
Documentation - Qingdao	Esther Xing	Senior Coordinator	86-532-66759768	esther.xing@cn.yusen-logistics.com
Account Executive - Ningbo	Amber Lin	Supervisor	86-574-87320844	amber.lin@cn.yusen-logistics.com
Operation - Ningbo	Gina Zhang	Coordinator	86-574-87320847	gina.zhang@cn.yusen-logistics.com
Operation - Ningbo	Happy Duan	Coordinator	86-574-87960272	happy.duan@cn.yusen-logistics.com
Documentation - Ningbo	Esther Luo	Clerk	86-574-87880126	ylngb.pt6@cn.yusen-logistics.com
Account Executive - Xiamen	Cynthia Wang	Associate Manager	86-592-8069163	cynthia.wang@cn.yusen-logistics.com
Operation & Documentation - Xiamen	Amy Zhou	Coordinator	86-592-8069171	amy.zhou@cn.yusen-logistics.com

CVS FREIGHT RATES BY CUBIC FOOT

Effective for direct import items presented or purchased in 2021, shipping (FDD) from March 1, 2021 -
February 28, 2022

ORIGIN	Full Container Rates (FCL)	CA Only FCL
Yantian	\$2.78	\$1.38
Shekou	\$2.80	\$1.40
Hong Kong	\$2.78	\$1.38
Ningbo	\$2.78	\$1.38
Shanghai	\$2.78	\$1.38
Xiamen	\$2.81	\$1.41
Qingdao	\$2.84	\$1.44
Fuzhou	\$2.94	\$1.54
Dalian	\$2.87	\$1.47
Xingang	\$2.88	\$1.48
Nanjing	\$2.91	\$1.51
India, Nhava Sheva, Kolkata	\$3.05	\$1.65
Indonesia, Jakarta - Surabaya	\$3.01	\$1.61
Korea, Busan	\$2.80	\$1.40
Malaysia, Port Klang	\$2.88	\$1.48
Taiwan, Kaohsiung	\$2.94	\$1.54
Thailand, Bangkok - Laem Chabang	\$2.91	\$1.51
Vietnam, Haiphong - Ho Chi Minh	\$2.92	\$1.52
Bangladesh, Chittagong	\$3.17	\$1.77
Cambodia, Sihanoukville	\$3.03	\$1.63
Philippines, Manila	\$3.00	\$1.60

Miscellaneous Rate for 2021 is .019X FOB

If an origin being considered for quotation is not on this list, please contact **Steve Genereux - Director Inbound Transportation** at 401- 770-4263, stephen.genereux@cvshealth.com or Elaine Lamoureux at 401-770-2556, elaine.lamoureux@cvshealth.com to insure the location is covered under CVS shipment contracts.

PRE-TICKETING FORMAT

****EXAMPLE****

CVS Retail Price	CVS	< Helvetica Bold
CVS Item Number	\$14.99	< Helvetica
Item Description*	#549550	< Helvetica
	12" Teddy Bear	< Helvetica
	>WHITE BACKGROUND	
	>BLACK LETTERING	

Please Note: LABEL SIZE SHOULD BE PROPORTIONATE TO PACKAGING

* Item Description is not necessary on ticket if description with weight/measure is already on item

The Category Manager will provide all pre-pricing information

PRODUCT MARKINGS

The following distribution statement exactly as shown must be printed on **ALL PRIVATE LABEL** merchandise that is shipped to CVS. Each individual item must be marked.

Distributed by: **CVS**
Woonsocket, RI 02895

Distributed by:	< Helvetica
CVS	< Helvetica Bold
Woonsocket, RI 02895	< Helvetica

Distributed by: **CVS** Woonsocket, RI 02895

CVS UPC/EAN REQUIREMENTS

- 1) CVS UPC/EAN Policy requires our suppliers to mark each item with a **UPC/EAN Bar Code** in compliance with all UCC Standards.
- 2) UPC/EAN should appear on the **BACK or SIDE PANEL**
Utilize front panel as last option
- 3) Bar code background and foreground must be of contrasting colors.
- 4) UPC/EAN must be scan-able within a maximum of two attempts

CVS PRODUCT QUALITY ASSURANCE TESTING PROGRAM

Product testing supports the commitment of CVS to offer quality products to its customers. CVS has partnered with Bureau Veritas Consumer Products Services, Inc. (BV), SGS Consumer Testing services (SGS) and Underwriters Laboratories (UL) for categories noted below, to establish a comprehensive testing program to monitor and ensure compliance with all applicable regulations as well as industry and corporate quality standards. As a part of this program, all products, in the form of final production samples, must be tested prior to purchase at BV, SGS or UL exclusively, unless approved by CVS. Other reports may be reviewed/considered by CVS QA in lieu of BV/SGS/UL in certain situations such as critical business disruption, missing FDD due to lab turnaround times etc... Reports must include all CVS protocol requirements to be considered for potential acceptance (See additional information regarding the transfer of certain testing results on page 22)

Overall CVS program questions should be directed to:

<p>Bureau Veritas Domestic Representative</p> <p>Lucy Feng Program Manager</p> <p>Bureau Veritas Consumer Products Services 175 Paramount Drive, Suite 303 Raynham, MA 02767</p> <p>P: 508.965.8230</p> <p>Lucy.feng@bureauveritas.com</p>	<p>Bureau Veritas Overseas Representative</p> <p>Heidi Law Program Manager</p> <p>Bureau Veritas CPS 7/F, Harbourside HQ, 8 Lam Chak Street Kowloon Bay, Kowloon, Hong Kong</p> <p>Mobile: +(852) 6312 5296 Office: +(852) 3693 3291</p>
<p>SGS Domestic Representative</p> <p>Reginald Harrison Consumer and Retail Global Key Account Manager SGS - North America Inc.</p> <p>291 Fairfield Avenue Fairfield, NJ 07004 Phone: 1 786 526 4742 reginald.harrison@sgs.com</p>	<p>SGS Overseas Representative</p> <p>Yolanda Chen Consumer and Retail</p> <p>Regional Key Account Manager, Retail Solutions SGS CSTC STS Co Ltd 4/F 1st building No. 889, Yi Shan Road, Xuhui district, Shanghai, China, 200233 Yolanda-TT.Chen@sgs.com Mobile: +86 151 518 46 969 Office: +86 021 6064 5278</p>
<p>UL Representatives</p> <p>Daniel Proia - Domestic Program Manager Daniel.proia@ul.com</p> <p>Underwriters Laboratories 85 John Road Canton, MA 02021</p> <p>Lillian Li - Overseas Key Account Manager, Consumer & Retail Services Lillian.li@ul.com</p> <p>UL VS Shanghai Limited 2/F, Bldg 1-C, Caohejing Hi Tech Pk. No.188 PingFu Rd., Xu Hui District, Shanghai Office: 86 21 2422 8312</p>	<p>These products <u>MUST</u> be tested by UL:</p> <p>ALL CVS Store Brand items with “CVS Logo” on packaging</p> <p>All Non-CVS Store Brand items should be tested by BV and SGS except for the following FDA Regulated categories:</p> <ul style="list-style-type: none"> *Food, human or pet *Over the counter drugs *Cosmetics including bath & fragrance products *Dietary Supplements *Medical Devices requiring a listing number

SAMPLE SUBMISSION - TEST REQUEST FORMS - PROTOCOL ACCESS

All suppliers must complete a “CVS Test Request Form” (TRF) and include it with test samples sent to testing labs. A separate TRF must be filled out for each CVS item number. Testing will not begin without complete TRF information. If items are purchased in a display, the display number should be referenced on the TRF along with all respective content numbers.

Bureau Veritas Test Request Form & CVS Protocol Access	SGS Test Request Form & CVS Protocol Access
<p>TRF – Using Google Chrome - go to the BV ONESOURCE Portal - https://www.bvonesource.com/wps/portal</p> <p>Any questions in regards to retrieving or filling out the test request form please contact the lab directly - Heidi.Law@us.bureauveritas.com and Vijay.Yadav@bureauveritas.com</p> <p>PROTOCOLS – Can be found at the following link; https://docushare.cps.bureauveritas.com/docushare/dsweb/View/Collection-3732 , user: cvsvend123, password: cvs123v</p>	<p>To request access rights to this site, contact the domestic SGS representative, listed on the previous page</p> <p>Go to SGSSonSite online at https://sgs.sharepoint.com/sites/ext-global-crs-cvs/Shared%20Documents/Forms/AllItems.aspx</p> <p>Enter the log in information provided by SGS</p>

The TRF information required includes:

- Sample Description
- Supplier Name and contact name and address
- CVS Item No.
- Sample Quantity
- Purchase Order (PO) Numbers
- Country of Origin
- Corrective Action Taken (For retests)
- Order Quantity (For retests)
- Original Test Report Number (For retests)

Samples submitted to the CVS designated testing lab should be **final packaged product**, representative of merchandise being shipped to CVS. If final packaging is not complete, one of the following alternatives may be submitted: mock up artwork or exact replica (must be actual size). Failure to provide either will result in the item being placed on hold by the respective laboratory.

While samples should be submitted no earlier than **eight (8) weeks prior** to the specified ship date, it is necessary to submit samples at least **four (4) weeks prior to the FDD** listed on purchase orders. During certain (peak) times of the year, samples submitted too close to the FDD for standard testing will have expedited premium testing performed by the lab at the submitter’s expense.

The availability of rush testing during peak season is limited. Peak season generally runs from June through August. All test labs will do their best to accommodate all rush submissions, but may not always be able to do so. You are encouraged to submit with as much advanced planning as possible, paying special attention to your FDD.

Suppliers should submit samples to the appropriate laboratory address. Please refer to CVS protocols for the specific sample size required for your product. Protocols can be obtained on-line from test lab website.

SAMPLE COLLECTIONS OF TOYS / JUVENILE OR FDA PRODUCTS

All items age graded 12 and under by CPSC definition, (including **all** toys), and FDA products can no longer be submitted to testing labs directly by suppliers. Products falling into those categories will require samples to be collected by the respective lab once production reaches at least 25% of the entire CVS order. Exceptions will be judged on a case by case basis if 25% of production is physically too large to store at the factory and/or testing must be completed sooner. Sample collection requests should be made at least one week in advance. Sample collection fees will be built into the cost of product testing paid by the supplier. You may contact the respective lab to ascertain the additional cost of the sample collection. Contact information is located on page 15.

SAMPLE SIZES

Initial Testing –

- 12 samples per style (for items appropriate for children under 3 years of age).
- 12 samples per style (Christmas Stockings)
- 3 samples per style (for items appropriate for children 3 years of age and over).

All samples are to be tested according to either the appropriate age grade as determined by testing lab or the labeled age grade, whichever is more stringent.

Assortments – Toys/Juvenile Products

To keep sample sizes for these items reasonable, the following compositing procedure for assortments has been developed. An assortment is defined as one CVS Item Number that contains more than one color or style. Use the below table for determination of the number of pieces required for testing based on the number of color/styles in an assortment and children’s age.

Number of color/styles in an assortment	Assortments appropriately age labeled for <u>children less than three years</u> of age	Total Sample Size	
		Assortments appropriately age labeled for <u>children three years of age and over and are identical in size and shape but vary in color</u>	Assortments appropriately age labeled for <u>children three years of age and over which vary in shape and/or size</u>
1	12 pcs	3 pcs	3 pcs
2	12 (6 pcs per color/style)	3 (1-2 pcs per color)	6 (3 pcs per style)
3	12 (4 pcs per color/style)	3 (1 pc per color)	9 (3 pcs per style)
4	12 (3 pcs per color/style)	4 (1 pc per color)	12 (3 pcs per style)
5	15 (3 pcs per color/style)	5 (1 pc per color)	15 (3 pcs per style)
6	18 (3 pcs per color/style)	6 (1 pc per color)	18 (3 pcs per style)

A minimum of three samples per shape and/or size in the assortment is required for testing.

Our testing labs are authorized to request up to 12 samples or individual components as needed from the manufacturers in order to complete testing, such as lead analyses. The supplier may choose to submit production samples or individual components to satisfy the request. Should 12 samples not be sufficient to conduct the analysis, the technical report will then state “Insufficient surface coating was present on the received sample(s). Consequently, the lead content analysis on surface coatings according to 16 CFR 1303, “Ban of lead-containing paint and certain consumer products bearing lead-containing paint”, was not conducted.”

Chemical Testing for Heavy Metals:

Products that are subject to chemical analyses for lead and other heavy metals per regulatory requirements, for example 16CFR 1303 for lead in surface paint or coatings, total of up to 12 samples or individual components may be required. For such products, the supplier may choose to submit production samples or individual components used for making the final product. In the event, 12 samples are not sufficient to conduct analysis; the test report will state "Insufficient surface coating was present on the received sample(s). Consequently, the lead content analysis on the surface coatings according to 16 CFR 1303, "Ban of lead-containing paint and certain consumer products bearing lead-containing paint", was not conducted".

TESTING FREQUENCY - All CVS Direct Import Merchandise

All merchandise being shipped to CVS **must be QA tested once every six months**. When the submission passes all testing, a Certificate of Compliance (COC) valid for six months from the date of issuance will be issued.

CVS reserves the right to request additional testing under circumstances such as, but not limited to the following:

- A new manufacturing site
- Changes in the country of origin
- Introduction of new regulations or standards
- Multiple production runs
- Amendments to existing regulations or standards
- Extended production schedules

CONSUMER PROTECTION SAFETY IMPROVEMENT ACT (CPSIA)

GENERAL CONFORMITY CERTIFICATE (GCC)

CPSIA legislation requires every manufacturer to submit a certificate stating their product complies with all applicable safety rules/bans/requirements. This document must:

- be in English and list full product description
- list name, address and phone number of the manufacturer
- list the date and place product was manufactured, and date and place of testing
- provide contact information of individual storing records
- list each applicable rule, standard, and/or ban

Certificates must accompany the product through the distribution chain, and must be available to the CPSC during inspections.

For items not requiring a GCC, CVS requires a Letter of Guarantee.

Under CPSIA, all children's products must also be permanently marked (tracking label) enabling the consumer to ascertain the manufacturer, location, batch and date of production of each item. Hang tags and adhesive labels are not allowed. For children's products as well as non-children's products with an applicable rule, ban or standard enforced by the CPSC, full protocol testing is required for the first set of purchase orders (POs). The "first set" includes CVS purchase orders for California (Patterson and La Habra) which usually are shipped two weeks later than the other POs. **All initial testing certificates will be valid for one month. Subsequent purchase orders placed within a six month period from the date of the initial test are required to undergo CPSIA testing only.**

Our labs will assist you in preparing necessary documents. Unless you have a written exemption from the CPSC, CVS requires full compliance to CPSIA.

RE-TESTS

If any item fails initial testing, a letter will be sent along with the fail test report, informing the supplier and/or manufacturer that they must notify the test lab to arrange for a sample collection for the retest. For a retest, the supplier must submit a Corrective Action Plan to the lab for review and approval. The same number of samples as initially tested from the production lot is required, unless otherwise authorized by CVS.

Manufacturers are responsible for informing the testing lab, via the space provided on the Test Request Form, if the submission is a retest. The previous test lab technical report number, the CAP and the total order quantity should be included on the Test

Request Form. A complete evaluation of the mechanical or chemical properties of the sample in which the previous failure occurred will be conducted during a retest.

Testing labs will only conduct the sample collection after **90% completion** of the manufactured or reworked merchandise. Additionally, a statement “Testing Lab Sampling is required for a retest” will be noted on the report.

For labeling only failures, two fully packaged samples will be required for a retest.

FACTORY INSPECTIONS & STORE AUDITS

CVS reserves the right to initiate factory site inspections and sample collections in the event that a supplier’s level of quality is falling below CVS standards. Additionally, CVS reserves the right to initiate domestic store audits to verify corrective action taken on failed merchandise. All costs associated with this process will be invoiced to the supplier. (Please see page 24 for more details regarding Factory Inspections/Audits)

TRANSFER OF RESULTS

The supplier may request transfer of certain test results for applicable relevant products from one lab when submitting samples to another test lab. For example, a supplier may request SGS lab to accept transfer of valid results from a previous BVCPs test report as long as those tests fall within **only** the categories below and are accompanied by appropriate documentation. In addition, the supplier should provide a letter of guarantee on company letterhead indicating that the product in testing is representative (same materials/process/facility etc.) to the item being sold to CVS. The below timeframes will vary based on documentation in question, therefore, any questions on accepting test reports across labs should be discussed with CVS before accepting.

All transfers from labs other than BV or SGS must be authorized by CVS.

- LHAMA Review (valid for 5 years)
- TRA Review applicable to cosmetics, health & beauty products, toys (valid for 1 year)
- USP 51 (valid for 5 years)
- USP 61 (valid for 2 years)
- FCC (valid for 3 years)
- FDA (valid for 1 year)

The submitted documentation required may include a letter of declaration or copy of the test report stating that above tests were done with PASS results. The declaration letter or test report must be accompanied with the copy of the original toxicologist’s report providing the name and signature, ID # of the toxicologist, and list of ingredients or sample identification for which the transfer of results is requested (not required for FCC).

If the submitted Pass test report or the supporting documentation is determined to be incomplete based on the CVS Import Testing Program requirements, the test lab receiving the samples will inform the supplier and proceed to conduct the additional testing required to issue a valid COC. If necessary, additional samples will be requested. Once the additional testing is completed, the test lab will issue a new COC to the supplier.

HOLD PROCEDURES

Samples will be placed on “Hold” and testing will not be initiated under certain conditions including, but not limited to the following:

- If test lab does not receive the correct number of samples.
- If the Test Request Form is missing or incomplete
- If the supplier has a delinquent account reflecting outstanding balances with test lab beyond 30 days

When samples are placed on “Hold”, the testing lab will notify CVS via its online web portal. The lab will notify the manufacturer within one business day that the samples are placed on “Hold” using a “Hold” memo outlining the reason. If

applicable, the manufacturers will then be responsible for supplying the lab with the additional samples or information required to initiate testing.

If an item is placed on hold due to missing EDI information, CVS will provide the testing lab with the information within one business day.

Testing will be initiated the day samples are released from "Hold" status. Test results will be available to CVS and the manufacturer within 24 hours of testing completion.

Testing delays due to 'on hold' conditions caused by suppliers will not warrant an extension of the shipping window.

TURNAROUND TIME

The turnaround time is noted on the last page of the protocol. Suppliers should not contact CVS or the test lab for results unless the due date has passed. Suppliers will be notified of test results by test lab on the report due date.

Test results in the form of a Certificate of Compliance (COC) or the Test Report will be available within six to seven business days after samples are either received at the laboratory or are taken off "Hold" status. The turnaround time may be extended for certain testing such as electrical and microbiological testing.

In the event "Rush Service" is requested, CVS and the manufacturer will receive results at the designated "Rush Service" turnaround time. Rush service levels include Next Two Days, Next Day and Same Day. Should same day service be required, the samples must be received at the laboratory before 10:00a.m. The supplier will be notified if a requested "Rush Service" cannot be honored by test lab. All Packaging/Labeling re-tests require Next 2 Day Rush Services at a minimum.

REPORTS

Test documentation in the form of a COC or a Test Report will be available within 24 hours of notification of the final test results. The COC or Test Report will be distributed as instructed by the supplier on the Test Request Form. **No booking of shipping appointments will be accepted without a valid COC by CVS's freight forwarder Yusen Logistics .**

INVOICING

Suppliers are responsible for all testing charges incurred for samples submitted under the CVS Import Testing Program. New suppliers may be required to prepay for their initial submission.

The testing lab will invoice the supplier at the conclusion of testing for each submission. Based on anticipated volume, CVS suppliers will receive a 15% discount from the testing lab price list that is in effect at the time of testing. Additionally, if a supplier decides to pre-test under the CVS program, a 15% discount will be applied at time of invoicing.

The general payment terms for both test labs are Net 30 days based on each supplier's credit history. Should a supplier's account become past due, samples will be placed on "Hold" status and both the supplier and CVS will be notified. CVS has agreed to assist the test labs in collecting payment from suppliers whose accounts are past due.

CALIFORNIA PROPOSITION 65

Suppliers are responsible for ensuring that their products meet CA Prop 65 requirements. CVS requires all products comply with all applicable Prop 65 settlement chemical content limits and will not accept products with California Prop 65 warning labeling unless labeling is required for all products regardless of formulation or measured chemical content. A complete list of the products and requirements can be obtained from the test lab by requesting the CA Prop 65 Supplemental Protocol. Additional information can be found on the CVSSupplier Portal.

Related site links are listed below:

California Attorney General: <http://ag.ca.gov/prop65/?PHPSESSID=ddd40c231f02f7782545aabf8e543c61>

California Tableware Safety Information: <http://www.dhs.ca.gov/childlead/tableware/twregs.html>

California Code of Regulations: <http://caselaw.lp.findlaw.com/cacodes/hsc.html> (Note: go to chapter 9, look up Title Health and Safety Codes – Division 104, Part 3, Chapter 9, Sections 108850-108915)

California Flammability Requirements: <http://www.bhfti.ca.gov/industry/bulletin.shtml>

California Proposition 65 Information, OEHHA: <http://www.oehha.ca.gov>

Consumer Product Safety Commission: <http://www.cpsc.gov/businfo/reg1.html>

Code of Federal Regulations: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1>

Federal Drug Administration: http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/

Litigation summary: <http://www.calprop65.com>

Prop 65 Summary documents: <http://www.oehha.ca.gov/prop65/background>

Prop 65 Chemical listing and legal news: <http://www.prop65news.com>

CVS FACTORY AUDIT PROGRAM

CVS has partnered with up with Underwriters Laboratories (UL) (www.UL.com) to perform factory audits on foreign factories supplying CVS with direct imported items.

There are up to five types of audits that may be performed on a factory, based on certain criteria:

1. Social Compliance – A Social Compliance audit will be performed in all international factories producing direct imported items for CVS.
2. Security – A Security audit will be performed in all international factories producing direct imported items for CVS. CVS Security audits are in line with Customs-Trade Partnership Against Terrorism (CTPAT) requirements.
3. GOOD MANUFACTURING PRACTICES (GMP) – Intertek GMP quality audits will be performed on all factories producing Store Brand FDA regulated items.
4. SUPPLIER QUALIFICATION PROGRAM (SQP) - Intertek SQP quality audits are performed on factories producing non-FDA Store Brand items.
5. SITE EVALUATION REVIEW (SER) – SER audits will be performed on factories manufacturing direct import items that have changed production sites after the PO was issued.

Social Compliance Audit & Security Audit

The CVS Ethical Sourcing and CTPAT Compliance program applies to all manufacturing facilities and all their subcontractors providing finished goods to CVS located outside the US and Canada.

The Social Compliance audit is based on the following assessment criteria:

Labor	Abuse, Coercion, Harassment; Disciplinary Action; Benefits; Child Labor, Young Workers, Apprentices/Trainees; Human Trafficking ; Discrimination; Forced Labor, Bonded/Slave Labor, Prison Labor; Freedom of Association and Collective Bargaining; Hiring and Termination; Remuneration; Working Hours; Postings; Privacy
Health and Safety	Licenses/Permits/Certifications; Postings; Risk Assessment; Risk Management; Governance; Education; Accidents; Chemicals and Hazardous Materials; Electrical; Emergency; Equipment Safety; First Aid; Personal Protective Equipment (PPE); Noise; Lighting; Ventilation and Temperatures; Potable Water; Sanitation; Food Preparation/Canteen; Child Care; Dormitory; Other Practices
Environmental	Licenses/Permits/Certifications; Postings; Risk Assessment; Risk Management; Education; General Waste; Hazardous Waste; Air Emissions; Noise Pollution; Other Practices
Management Systems	Certifications; Governance; Compliance; Responsibility; Education; Performance; Grievance Mechanism
Ethics & Business Integrity	Integrity; Bribery Attempt; Bribery and Facilitation Payments

The Security audit is based on the following assessment criteria:

Business Partner Requirements	Foreign manufacturers must have written and verifiable processes for the selection of business partners including, truckers, subcontracting facilities, import product suppliers (parts and raw material suppliers, etc.) and develop and implement a sound plan to enhance security procedures.
Physical Security	All buildings must be constructed of materials which resist unlawful entry and protect against outside intrusion.
Access Controls	Unauthorized access to the shipping, loading dock, and cargo areas must be prohibited. Visitors refers to all business clients, including the CVS Pharmacy, Inc. suppliers, delivery drivers, etc.
Procedural Security	Protocols for the handling of incoming and outgoing goods must include protection against the introduction, exchange, or loss of any legal or illegal material.
Truck & Container Security	Procedures must be in place to verify the physical integrity of the container and/or truck structure prior to stuffing, to include the reliability of the locking mechanisms used on the doors.
Personnel Security	Consistent with local laws, factories should conduct employment screening and interview of prospective employees to include periodic background checks and application verifications.
Information Technology Security	Computers and other applicable technologies must use individually assigned accounts that require a periodic change of password. Procedures and policies must be documented and shared with employees in the form of training.
Education and Training Awareness	A security training and threat awareness program must be in place to educate employees on the threats posed by terrorists and contraband smugglers. These programs must encourage active employee participation in recognizing and reporting internal conspiracies, including maintaining cargo integrity and procedures for challenging individuals that are prohibited from accessing specific areas of the facility.

Supplier/Factory Audit Process/Steps:

- All suppliers are required to register their primary factory(-ies) and Tier 1 subcontractors with UL Responsible Sourcing via the clientportal.ul.com **immediately upon receipt of purchase orders.**
- UL will perform the required audits within a designated time period
 - CVS may accept specific third-party audit reports that meet a certain criteria. Please contact dustin.burns@cvshealth.com regarding the CVS third party acceptance policy.
- A report package which will include the official report and Supplier Letter will be issued 5 business days after each audit is completed. The Supplier Letter contains all of the necessary information to book the shipment with Yusen.

Note: No product will be allowed to ship without a valid and acceptable audit report
- The shipping approval for Social Compliance audits is outlined below:

SOCIAL COMPLIANCE AUDIT GRADE	SHIPPING APPROVAL
Access Fully Denied	Item(s) NOT allowed to ship.
Zero Tolerance	Item(s) NOT allowed to ship.
Alert Notification	Item(s) NOT allowed to ship.
Critical	Item(s) NOT allowed to ship.
High Risk	Item(s) allowed to ship.
Intermediate Risk	Item(s) allowed to ship.
Low Risk	Item(s) allowed to ship.

- The shipping approval for Security audits is outlined below:

SECURITY AUDIT GRADE	SHIPPING APPROVAL
Access Fully Denied	Item(s) NOT allowed to ship.
Zero Tolerance	Item(s) NOT allowed to ship.
Alert Notification	Item(s) NOT allowed to ship.
Preferred	Item(s) allowed to ship.
Subject to Improvement	Item(s) allowed to ship.
Needs Improvement	Item(s) allowed to ship.

- Factory will be required to provide a Corrective and Preventive Action (CAPA) within 30 business days
- CVS reserves the right to cancel Item and PO if the audit results in a grade of Critical, Alert Notification, Zero Tolerance or Access Fully Denied.

Alert Notification:

Alert Notification findings are serious findings cited during an audit that can lead to factory probation. CVS allows the supplier and factory the opportunity to remediate these findings, provided it is done so immediately. The following findings are considered Alert Notification findings:

- Temporarily Blocked Emergency Evacuation Exits and/or Pathways (not corrected during the audit)
- Locked Emergency Exits
- Passport Retention
- Missing Business License
- Non-disclosure of finished goods subcontracting (Tier 1 subcontractors)
- Discrimination with regard to age, gender, minority status and/or other protected classes and upholds the right to freedom of organization. Workers should not be subjected to medical testing (e.g. pregnancy testing of female workers)
- Non-threatening and non-coercive harassment of employees

The Alert Notification process is as follows:

- Within 24 hours the Supplier must agree to remediate the finding
- Within 48 hours the Supplier must provide photographic evidence that the finding has been resolved
- CVS will conduct an unannounced verification audit within 30 days to ensure this is not a reoccurring issue

Items cannot ship until all of the above actions have been taken.

Zero Tolerance:

Zero Tolerance findings are non-compliance findings identified during the audit that will result in immediate Probation of the factory and cancellation of all orders.

Zero Tolerance findings:

Child Labor	The hiring of workers in a factory who are below the minimum age requirement based on country local law, or the age of 16 (whichever is higher).
Forced, Prison Labor, Human Trafficking	The use of employees who are imprisoned, bonded, or indentured either to the factory itself or to a broker. This includes the presence of North Korean workers. (i.e. employees utilized in a manner not in accordance with International Labor Convention 29).
Abuse and Harassment	There is evidence of either sexual, psychological, physical, verbal harassment, abuse, intimidation and/or bullying occurring at the factory.
Life Threatening Conditions	There are permanently blocked or locked emergency evacuation pathways/aisles to exit/ doors/ stairways.
Bribery	There is evidence of the factory bribing or attempting to bribe the auditing team or CVS Pharmacy, Inc. staff in any manner.
Confirmed falsified audit report and/or business license	There is evidence of the factory submitting falsified audit reports or business license to circumvent the requirements of the social and/or security audit.
Intentional nondisclosure of finished goods subcontracting	The factory shall not use a subcontractor to manufacture finished goods (Tier 1) without first disclosing the subcontractor to the CVS Pharmacy, Inc.

Factory Auditing Frequency and Timeline:

Initial audits are required to be conducted prior to a PO being shipped. Follow-up audits are required to be performed based on factory performance. Please contact dustin.burns@cvshhealth.com for more information regarding the follow-up audit.

Reporting:

The Supplier, Factory and CVS will receive a copy of the audits report within 5 days of the audit.

Invoicing:

Suppliers are responsible for all factory audit charges (paid directly to UL), including travel expenses. After the audit is conducted, UL will email an invoice within 48 hours communicating the payment details including the audit costs to the supplier and factory.

GOOD MANUFACTURING PRACTICE (GMP)

Good Manufacturing Practice (GMP) audit involves an evaluation of the systems and processes used by a company to maintain and control product quality. Areas that are evaluated include, but are not limited to, personnel qualification, equipment control, material procurement and handling, production controls, complaint handling and management responsibilities. If the product is regulated by the FDA, the systems and processes evaluated during an audit can be found in the Code of Federal Regulations Title 21. GMP audits will be performed on factories that manufacture items for CVS such as food, cosmetics, over-the-counter medications, medical devices, other FDA regulated items and store brand items. also be performed on randomly selected factories as listed below: (not currently being performed)

UL GMP Certification Program – Administered under UL SQAC’s Retail Certification Program (RCP), this program is designed for suppliers who produce regulated product, or suppliers who are expected to maintain a more advanced level of GMP. Such products include: Over-The-Counter Drugs, Dietary Supplements, Food, Infant Formula, Cosmetics and Medical Devices.

UL conducts GMP audits according to the number of days determined in the supplier’s onboarding and as verified annually during application review procedures. Only those auditors qualified under UL’s accredited auditor competence program are utilized to conduct audits under the RCP.

There are three types of nonconformance under the UL GMP audit program:

Minor

Failure to adhere to an approved policy, procedure, instruction or process, or failure to comply with required regulations where:

- There is insufficient evidence to be classified as a Major;
- There is little potential for significant health risk to the consumer;
- The quality, strength, identity, purity of the product has not been compromised

Major

A systemic failure of any system, procedure or process or failure to comply with required regulations that would have significant impact on the quality, strength, identity or purity of the product or the lack of a system, process or procedure required by regulations.

Critical

A critical nonconformity will or may result in a significant risk of producing the product, that when used in a finished product is harmful to the user.

Nonconformance number and severity will impact outcome, but all issued nonconformances, regardless of outcome, require an acceptable root cause analysis and CAPA plan.

UL maintains a controlled form for the collection of facility CAPA, and this is provided to the auditee on the last date of the audit. At that point, the supplier is expected to provide root cause analysis and CAPA plan, with responsible personnel and target completion date, within 30 calendar days.

Auditors will evaluate Root Cause and CAPA plans and are expected to reject those CAPA that are not in conformance with the program expectations. UL’s program allows for up to 45 calendar days to achieve acceptable root cause and plans. This usually allows for 3 rejection/resubmission cycles after the first 30 day submission. Where acceptable CAPA are not provided within 45 calendar days, the facility is denied certification and must start the audit program over. CVS will be notified before a supplier reaches this point. If the supplier requires an extension on the plans due to extenuating circumstances, this must be approved by UL and communicated to CVS.

The type and/or number of nonconformances issued on an audit will determine whether a follow up activity will be required of a GMP site. This will be indicated preliminarily on the Audit Summary left at the close of the audit. The intent of the follow up audit is to verify closure of nonconformances through review of evidence. Follow up activities may be 1 or ½ day events, and may be onsite or offsite, dependent on the type of nonconformances and CAPA that must be verified.

UL Technical Audits Program (TAP) – This program is designed for those suppliers who are producing non-regulated items. The UL Technical Audit is not certificated, but follows the program procedures that are maintained and controlled within UL’s document control system. This program still requires an audit annually for CVS.

UL conducts TAP audits according to the number of days determined in the supplier’s onboarding and as verified annually during application review procedures.

There are three types of nonconformance under the UL TAP audit program: Minor, Major and Critical. The classification of nonconformance is dependent on the level of compliance as indicated by the auditor against the requirement, as well as the assigned risk level to the requirement. There are 4 levels of possible compliance, defined as follows:

Level of Compliance	Means of Assessing Compliance
3 (full compliance)	<ul style="list-style-type: none"> • Comprehensive evidence is available during the audit; • Continuous improvement can be demonstrated, data analysis is conducted and records are kept; • Documented procedures are available and effectively implemented; • Records are well maintained as defined; • Relevant employees have good understanding of their duties; • Management takes proactive actions and quality tools are used effectively.
2 (Partial compliance)	<ul style="list-style-type: none"> • The facility has a process in place. It has some lapses in monitoring and effectiveness. There are some deviations in consistent application of the process which means the requirement of the clause is not fully met at all times.
1 (Partial compliance)	<ul style="list-style-type: none"> • The site has a process in place, but it is poorly established, poorly monitored or does not effectively address the requirement of the clause.
0 (No compliance)	<ul style="list-style-type: none"> • Full non-compliance. The site does not have an effective process in place to meet the clause requirement.

A nonconformance against a high-risk requirement, with a low level of compliance, will result in a higher classified nonconformance. Nonconformance number and severity will impact outcome, but all issued nonconformances, regardless of outcome, require an acceptable root cause analysis and CAPA plan.

UL maintains a controlled form for the collection of facility CAPA, and this is provided to the auditee on the last date of the audit. At that point, the supplier is expected to provide root cause analysis and CAPA plan, with responsible personnel and target completion date, within 30 calendar days.

Auditors will evaluate Root Cause and CAPA plans and are expected to reject those CAPA that are not in conformance with the program expectations. UL’s program allows for up to 45 calendar days to achieve acceptable root cause and plans. This usually allows for 3 rejection/resubmission cycles after the first 30-day submission. CVS will be notified before a supplier reaches the point of 45 calendar days. If the supplier requires an extension on the plans due to extenuating circumstances, this must be approved by UL and communicated to CVS

The UL Technical Audit will result in a letter and color grade from A to D. Overall Rating is indicated in the table below, in relation to the letter grade achieved.

Overall Rating	
A (GREEN)	High Performance/Meets Expectations
B (YELLOW)	Medium Performance/Further Improvement Needed
C (ORANGE)	Low Performance/Significant Action Required
D (RED)	Very Low Performance/Urgent Action Required

The type and/or number of nonconformances issued on an audit will determine whether a follow up activity will be required of a non-regulated site. The outcome of the audit will be visible on the audit report provided to the facility.

CVS & GOVERNMENT AGENCY REQUIREMENTS

CVS PHARMACY CTPAT REQUIREMENTS FOR PRODUCT SUPPLIERS

The CVS Import Department sends out a copy of the CVS Pharmacy CTPAT Requirements For Product Suppliers to all new suppliers. The supplier is to agree to these requirements, sign and send back the last page of the document within seven business days.

The Agreement is to be signed only once unless:

- There are updates to your supply chain
- There are updates to the CTPAT program

The agreement states in part that the supplier:

“Agrees to develop and implement, within a framework consistent with the Customs Trade Partnership Against Terrorism (CTPAT) security criteria, a verifiable, documented program to enhance security procedures throughout its supply chain process, including, but not limited to, its manufacturing business partners. Where the Product Supplier does not exercise control of a production facility, transportation or distribution entity, or process in the supply chain, the Product Supplier agrees to communicate the CTPAT security criteria to its manufacturers and transportation/distribution service providers and, where practical, condition its relationships to those entities on the acceptance and implementation of the CTPAT security criteria.

“The Product Supplier agrees to communicate CVS Pharmacy, Inc.’s supply chain security and CTPAT procedures, and security criteria to its manufacturers in a documented and verifiable format that can be made available upon request, and it understands that failure to do so may jeopardize its business relationship with CVS Pharmacy, Inc.”

FOOD AND DRUG ADMINISTRATION

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. CVS will request additional information needed for FDA regulated items.

US DEPARTMENT OF AGRICULTURE AND THE LACEY ACT

The Lacey Act combats trafficking in “illegal” wildlife, fish, and plants. The 2008 Farm Bill (the Food, Conservation, and Energy Act of 2008), effective May 22, 2008, amended the Lacey Act by expanding the law banning commerce in illegally sourced plants and their products.

Requirements: The Lacey Act now, among other things, makes it unlawful to import certain plants and plant products. The Lacey Act requires a Plant and Plant Product Declaration form (PPQ 505) for all wooden/paper products that fall within the scope at the time of importation.

- ▶ Suppliers must submit a completed Plant and Plant Product Declaration Form with the commercial documents, or list the information on the commercial invoice by item

The PPQ 505 can be found at: <http://www.aphis.usda.gov/library/forms/pdf/ppq505.pdf>

The form must contain the following information:

1. The scientific name of the plant
2. Value of the importation
3. Quantity of the plant
4. The name of the country from where the plant was harvested.

For paper and paperboard with recycled content, the declaration must also include the percentage of recycled content. Declaration requirements and more information are located on the cvssuppliers.com website at:

<http://cvssuppliers.com/requirements/import-information> under “Lacey Act Info” and “Lacey Act Letter.”

OZONE DEPLETING CHEMICALS

The Internal Revenue Service (“IRS”) requires importers such as CVS to obtain specific documentation regarding the use of Ozone Depleting Chemicals (ODC) by its suppliers. CVS requests your cooperation in substantiating whether or not ODC were used to manufacture those certain products referenced within the Harmonized Tariff Schedule (“HTS”) numbers.

CVS will identify whether a supplier is providing products within certain HTS numbers. If and when such products are identified, the supplier will be contacted via a form letter. This letter will include the list of items sold to CVS and will address the IRS documentation requirements. The supplier must respond within 30 days from the date of the form letter. To further validate if ODC were or were not used in the manufacturing process, the following information will need to be provided:

- Identify the major cost component of each item and the name and country of the foreign manufacturer(s).
- Describe in detail the policy of the foreign manufacturer’s country, in response to the Montreal Protocol on Substances that Deplete the Ozone Layer, to encourage the reduction in production and use of ozone depleting chemicals. If the foreign manufacturer is not aware of their country’s policy, have them state that fact.
- Describe, in detail, the new alternative product of the replacement technology used instead of the ODC process. The description should include the type of equipment involved, the month and year the new technology was placed in service, and the name and address of the firm from whom the new technology was purchased.
- Provide documentation, including laboratory methodology, of any laboratory testing performed to verify the assertion that no ozone depleting chemicals are used in the manufacturing process, if applicable.
- English translation required for any response made in a foreign language.

Subsequent purchases of identified products made by CVS from the supplier MUST include all documentation as outlined above. Failure to comply with CVS requests for IRS documentation will result in review of CVS Supplier agreements and monetary consequence of applicable IRS Tax.