## 1.0 Purpose

The purpose of this procedure is to ensure the receipt, examination, storage, issuance, return and reconciliation of labels are controlled according to 21 CFR 211.125 & ICH Q7 9.3.

## 2.0 Scope

The definition of labels at the Repackaging facility pertains to cartons and pouches.

## 3.0 Responsibility

Expeditors – notify QA of incoming labels, place incoming labels on Quality Hold, transport labels to and from production floor, and bring receiving documents to Inventory Analyst.

QA – inspection of labels for identity and conformity, release for use and, approval of label discrepancy investigations.

Operators – record quantity of labels consumed and rejected pre and post production.

Supervisors – oversee the reconciliation of the quantities of labels issued, used and returned.

Inventory Analyst - responsible for receiving inventory, cycle count and label discrepancy investigations.

## 4.0 Safety Considerations

Safety shoes and safety glasses are required when working in the plant.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

## 5.0 Materials/Equipment

Incoming Raw Material Placards
Product /Stock Transfer Sheets
Product Changeover Sheets
Inventory Control File

## 6.0 Procedure

**Reception**

- Expeditor will unload incoming truck and place labels (cartons & pouches) into the designated Quality Hold area or placard with *Incoming Raw Material Hold (Q15-FM-100-012)* placards if the Quality Hold area is full. This designation of Quality Hold is a visual instruction that informs any associate that this material has not completed the incoming raw material inspection and is NOT available to be used in production.

- Expeditor will take BOL from driver and Master Packing Slip(s) from pallet(s) and verify incoming quantities. Once quantities are verified, Expeditor will sign and date BOL and return to driver. The Master Packing Slip(s) are signed, dated, and turned into Inventory Analyst along with any individual pallet Packing Slip(s). Inventory Analyst will compare product and quantity received against product and quantity ordered. Inventory Analyst then receives product quantity against the PO number by the date of receipt in the Inventory file.

**Examination**

- Expeditor will notify Quality of incoming labels to be inspected and released for use in production.
- The Quality Unit will use *Incoming Raw Materials Procedure (Q15-FM-100-012)* to examine and inspect labels for identity and conformity against a specified master label provided by customer. Once approved, *Incoming Raw Material* placards will be replaced with *Quality Approved (Q13-FM-100-006)* placards.
- Incoming labels that do not meet specifications will be rejected and *Quality Rejected (Q13-FM-100-007)* placards will be placed on affected pallets. Quantity rejected is not received into inventory and is returned to supplier.
- Obsolete and outdated labels will be destroyed at local recycling facility.

**Storage**

- Labels will be stored following FIFO (First In First Out) until needed to produce an order. Access to the label storage area is limited to authorized personnel.
- As labels are needed for production, Supervisor will inform Expeditor which labels need to be retrieved. Expeditor will retrieve the identified label in the appropriate quantity to complete the order.
- Expeditor will note on the Product/Stock Transfer sheet the label name and quantity to be transferred to production. Expeditor shall also note which area the labels will be transferred from and which area they will be transferred to.
- Expeditor will transfer requested labels and give the Product/Stock Transfer sheet to the Supervisor or the Inventory Analyst so that the label location and quantity can be updated in the inventory system.

**Issuance**

- Supervisor will record the quantity of labels issued on the Changeover sheet. Label specifics including, but not limited to, bar code, UPC, date code and expiry date are documented on the Changeover sheet which is included in the batch record.
- Production will produce the exact number of cases that are required to complete the order. If there are any excess filled labels at the end of the production run, these filled cartons and pouches shall be packed, palletized and properly identified with the correct lot number for the production date and expiry, if applicable. This material will need to be wrapped and marked with correct case count and placed into inventory.

- Operator will record the quantity of labels consumed to complete an order on the Changeover sheet. Label waste generated during production will be disposed of.

**Return**

- The quantity of unused labels remaining after production is complete shall be recorded on the Changeover sheet. The unused labels are sealed with shrink wrap plastic on existing pallet. Then the quantity and label identification of the remaining labels is noted on the pallet to prevent mix-ups during storage.

- Expeditor will note on the Product/Stock Transfer sheet the label name and quantity to be returned to storage. Expeditor shall also note which area the labels will be transferred from and which area they will be transferred to.

**Reconciliation**

- Waste label amounts are to be counted on each production line and the wasted label counts are to be recorded on the changeover sheet and placed on the Compactor Waste Form (*R13-FM-100-044*) when disposed of. This form is then turned in with the daily batch record. The waste percentage should be noted on the changeover form.

- Label yield will be calculated from the Product Changeover Sheet. If the yield is less than 95% an investigation should be completed by Supervision, Inventory Analyst and Quality Unit. Investigation should result in the proper explanation of a yield less than 95%. The investigation will be documented on a *Label Discrepancy Form (Q15-FM-100-013).* Completed documentation will be submitted to and retained by the Quality Unit.

- Cycle counts will be conducted monthly by Inventory Analyst with the assistance of production employee(s).

## 7.0 Reference Documents

*Incoming Raw Material Hold* placard *(Q15-FM-100-012)*
*Quality Approved* placard *(Q13-FM-100-006)*
*Quality Rejected* placard *(Q13-FM-100-007)*
*Label Discrepancy Form (Q15-FM-100-013)*
*Compactor Waste Form (R13-FM-100-044)*
Product/Stock Transfer
Product Changeover Sheets

## 8.0 Change Information

Updated to include *Label Discrepancy Form* in the Reconciliation section.