

	Standard Operating Procedure Creating New Packaging Component Specifications	SOP Number E-708	Revision 0
		Effective Date 07/02/18	Page Page 1 of 7
Written by/ Date <i>Spina Encinon 06/14/18</i>	Reviewed by/ Date <i>Melixa Menso 06/19/18</i>	Approved by/ Date <i>Spina Encinon 06/19/18</i>	
Title: Quality Specialist	Title: Process Engineer	Title: QA Manager	

1.0 Purpose

The purpose of this SOP is to describe the procedure used in maintaining and reviewing new incoming packaging component specifications documentation to ensure both required quality standards and regulatory requirements are met for safe food contact (Dietary Supplement), Cosmetic and OTC products.

2.0 Scope

This procedure applies to all packaging components /materials used to contain food related product/material or any other finished product material manufactured by Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of Purchasing, Process Engineers, Quality Control and Quality Assurance, or designee to manage and ensure overall compliance with this procedure.
- 3.2 It is the responsibility of Purchasing to send as well as notify the Process Engineer of any updates on vendor provided documentation associated with packaging components including: technical drawing specifications, regulatory information indicating the container is safe for food /product contact (Certificate of Compliance), and the PO containing the Packaging Component ID number based on the type of component.
- 3.3 It is the responsibility of the Process Engineer or designee to create an internal packaging component specification sheet based off of the documentation provided for each component, and to ensure that this documentation is approved and signed by Quality. The Process Engineer will notify Quality Control Management when documentation is completed and approved. The Process Engineer will maintain all records of all packaging component specifications including the Packaging Component index.
- 3.4 It is the responsibility of the Quality Systems Manager or designee to ensure documentation submitted containing the data and specifications for each packaging component is approved by Quality and submitted electronically to Document Control. These approved documents will be made available to the Quality Control Supervisor and Incoming Inspection Department.
- 3.5 It is the responsibility of Quality Assurance to ensure the completed packaging component specification meets all internal and regulatory requirements prior to approval.
- 3.6 It is the responsibility of Production, Quality Systems, Quality Assurance and Document

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Control management to ensure this procedure is implemented and followed.

4.0 Definitions

- 4.1 **Packaging Component** – any type of packaging component (bottles, caps, scoops, desiccants, etc.) used as a final packaging container that comes into contact with finished product.
- 4.2 **PO** - Purchase Order provided by Purchasing.
- 4.3 **Packaging Component ID** – an internal number assigned by Accounting to identify a type of packaging component.
- 4.4 **Packaging Component Specification Form** – an internal specification form listing component description, component dimensions, the packaging component ID, and manufacturer.
- 4.5 **Certificate of Compliance - (C of C)** - regulatory documentation used to ensure component coming into contact with finished product is safe for food use.
- 4.6 **Packaging Component Index** – a reference document listing the Packaging Component ID and its description based on specification.
- 4.7 **AVL** – Approved Vendor List

5.0 References

- 5.1 E-101, SOP, Warehouse and Inventory Control
- 5.2 E-601, SOP, Vendor Qualification
- 5.3 C-502, SOP, Record Storage, Retention, and Destruction

6.0 Procedure

- 6.1 Purchasing will notify the Process Engineer or designee upon receiving a new packaging component. The Process Engineer will initiate the creation of a new packaging component specification sheet according to documentation provided consisting of: PO containing Packaging Component ID and product description, technical specifications and drawings for materials associated with the component, and CofC compliance documentation acknowledging if the component is safe for food use/intended use (i.e. meets FDA Food, Drug and Cosmetic Act Federal Regulations).
 - 6.1.1 The Process Engineer will verify with Purchasing if the packaging component supplier is an approved vendor on the Approved Vendor List prior to proceeding with creating the specification.

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6.1.1.1 If the vendor providing the component is not on the list, Purchasing will initiate a Vendor Evaluation Form (E-601-F2) and forward on to the Quality Specialist begin the vendor qualification process.

6.1.1.2 Upon completion of the vendor qualification, the Quality Specialist will notify the Process Engineer and Purchasing of adding the new vendor to the Approved Vendor List.

6.2 Creation of the Packaging Component Specification Sheet

6.2.1 Create a new folder in Technical Drawing and Specifications located on the F: drive, naming the folder by Packaging Component ID assigned via PO and save all technical documents provided by Purchasing electronically into this folder for reference. (*F:/Doc Control Only/Technical Drawings and Specifications*).

6.2.1.1 Print a hardcopy of all technical documentation received by Purchasing. Examine the required documentation is present including all regulatory (CofC) information. If not provided, request Purchasing to contact vendor to provide a copy.

6.2.1.2 Write the Packaging Component ID on all hardcopies of the documentation associated with the corresponding Packaging Component ID. (Example: Bottle – PB0050; Cap – PC0100; Scoop – PK0200). Highlight documentation indicating the component is safe for food / intended use for quick reference.

6.2.2 Open the corresponding template form (See Attachment 8.1) based on the type of packaging component to be completed and save into the newly assigned Packaging Component ID folder (*Example: PC0244 Packaging Component Specification Form*).

6.2.2.1 Enter all pertinent specification information for the component into the Packaging Component Specification Form using the technical and regulatory documentation provided.

Note: Review all fields for accuracy noting all dimensions (significant figures), units of measure (convert mm to inches if applicable), as well as all other fields agree with what is listed on the technical documentation. Should the documents not be in English or translatable, contact Purchasing for additional information.

6.2.2.2 The Process Engineer or designate will sign off on the Packaging Component Specification Form and attach all technical/regulatory documentation to present to Quality for final review.

6.3 Completing the Packaging Component Specification Review Process

6.3.1 Upon completion of the documentation, the Quality Specialist or designee will

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verify if the packaging component was purchased from a qualified vendor as listed on the AVL, examine the documentation for accuracy and completeness of the Packaging Component Specification form, and assure that all other required regulatory information is provided to ensure the component is safe for food use/intended use.

6.3.2 Upon approval, the Quality Specialist or designee will sign and date the Packaging Component Specification form, returning all documentation to the Process Engineer or designate to file.

6.3.2.1 The Process Engineer or designee will ensure all documentation returned from Quality is approved with signature and date prior to creating an electronic file.

- The Process Engineer will scan the verified documentation and create an electronic file (PDF) including all required documentation and save it to the original Packaging Component ID folder.
- The electronic copy of the data and specifications for this documentation will be forwarded to the Quality Systems Manager.
- The original hardcopies of the approved documentation scanned will be retained by the Process Engineer and available for reference.

6.4 Updating the Packaging Component Index for New Components

6.4.1 The Process Engineer or designee will update the Packaging Specification Component Index to reflect the new component (to include Item ID, Category, and description).

6.4.1.1 Based on the component type, the new component will be added and saved to the corresponding spreadsheet. (*F:/Doc Control Only/Technical Drawings and Specifications/Packaging Component Specification Index*).

6.4.1.2 A hardcopy of the Packaging Component Specification Index will be updated, printed and stored in the designated Packaging Component Specification binder as a reference guide for Quality, Production and other departments (as applicable) each time a new packaging component is added to the library.

6.5 Records will be retained per SOP C-502 (Record Storage, Retention, and Destruction).

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/14/18	New procedure.	N/A	L. Erickson

8.0 Attachments

- 8.1 Example of Packaging Component Specification Sheet – Bottle (PB)
- 8.2 Example of Packaging Component Specification Sheet – Cap (PC)
- 8.3 Example of Packaging Component Specification Sheet – Scoop (PK)

Attachment 1 - Example of Packaging Component Specification Sheet – Bottle (PB)

Packaging Component Specification 400cc Cobalt Blue PET Packer Round 45/400 Bottle	
Specification Item	Value
Height:	5.125 ± .050
Width:	2.875 ± .030
Mouth Opening:	1.631 ± .015
Weight (gr):	37.3 ± 2
Chemical Composition:	PET
Color:	Cobalt Blue
Suitability of Material:	Confirmed
*Technical Drawing Attached from <i>Paradigm Packaging</i>	

Ref. No. PB0175

Reviewed and Approved By: _____

QC Manager / Designate

_____ Date

Attachment 2 - Example of Packaging Component Specification Sheet – Cap (PC)

Packaging Component Specification Black Ribbed Mold-Rite Cap 45/400 Lift and Peel	
Specification Item	Value
Height:	0.445" ± .010
Width:	1.865" ± .010
Weight (gr):	3.9 ± 1.5
Chemical Composition:	Polypropylene
Color:	Black
Type:	Ribbed with Smooth Top Cap Lift and Peel
Suitability of Material:	Confirmed
*Technical Drawing Attached from <i>Mold-Rite Plastics Inc.</i>	

Ref. No. PC0153

Reviewed and Approved By: _____

QC Manager / Designate

_____ Date

Attachment 3 - Example of Packaging Component Specification Sheet–Desiccant (PK)

Packaging Component Specification 1.0 Gram Silica Gel Desiccant	
Specification Item	Value
Width:	0.9251" ± .0787"
Length:	1.4960" ± .0787"
Net Weight	1.0gr ± 10%
Packaging Type:	Tyvek®
Composition:	Silica Gel
Color:	White
Suitability of Material:	Confirmed
<small>*Technical Drawing Attached from <i>DryPak Industries</i></small>	

Ref. No. PK0105

Reviewed and Approved By: _____
Quality Manager/Designee
Date