HBI Ion Labs	Standard Operating Procedure Printed Packaging Compliance Procedure	SOP Number C-708	Revision 10
		Effective Date 07/16/25	Page Page 1 of 8

Written by/ Date	Reviewed by/ Date	Approved by/ Date
Jessica Vega 07/10/25	07/09/25 Vanelana Shukla	07/11/25
Title: QA Compliance Supervisor	Title: Document Control Supervisor	Title: QA/QC Director

1.0 Purpose

This procedure establishes a process for creating, reviewing, and approving all printed packaging components to ensure compliance.

2.0 Scope

This procedure applies to all products packaged by Ion Labs that require labels, cartons, inserts, shrink sleeves, or display trays, otherwise referred to as printed packaging components.

3.0 Responsibility

3.1 It is the responsibility of Label Compliance, R&D, Production Control, and Account Managers to determine the appropriate packaging size, utilizing the purchase order and/or customer supplied specifications.

3.2 It is the responsibility of Label Compliance, R&D, and Quality to ensure that all printed packaging components conform to FDA regulations and other required legal standards.

3.3 It is the responsibility of Label Compliance to ensure regulatory documentation requirements are met during the creation of printed packaging materials.

3.4 It is the responsibility of Account Managers to obtain printed packaging information and art files from the customer.

3.5 It is the responsibility of Label Compliance to ensure that printer proofs and final printed packaging are reviewed by applicable departments and to act as a liaison between the Purchasing and Sales departments, as well as vendors and customers.

4.0 Definitions

4.1 **LPC** – Label Packaging Component

4.2 **SAP** – Systems, Applications, and Products; enterprise resource planning software which manages day-to-day business activities

4.3 **SKU** – Stock Keeping Unit

4.4 **MBR** – Master Batch Record

4.5 **DC** – Document Control

4.6 **R&D** – Research and Development

5.0 References

5.1 C-502, SOP, Record Storage, Retention, and Destruction

5.2 C-403, SOP, Change Control Procedure

5.3 E-101, SOP, Warehouse and Inventory Control

5.4 E-204, SOP, Receiving Process for Raw Materials and Packaging Components

5.5 E-801, SOP, Return of Materials and Destruction of Non-Hazardous Waste Materials

5.6 C-708-F1, Form, Printed Packaging Art and Revision Approval

5.7 C-708-F2, Form, Printer Proof Comparison

5.8 C-708-F3, Form, Printing Packaging Master File

5.9 C-708-F4, Form, Printed Packaging Receiving Inspection

5.10 C-708-F5, Form, Printed Packaging Receiving Inspection – Extended Criteria

5.11 21 CFR Part 101.36, Nutrition Labeling of Dietary Supplements

5.12 21 CFR Part 101.9, Nutrition Labeling of Food

5.13 21 CFR Part 701, Cosmetic Labeling

5.14 21 CFR Part 201 Sub Part B, Labeling of Prescription Drugs and/or Insulin

5.15 21 CFR Part 201 Sub Part C, Labeling of OTC Medications

5.16 www.fda.gov/animal/veterinary/resources

5.17 www.aafco Pet Food Labeling - General

6.0 Procedure

Note: Supplement Facts (or equivalent) and printer proofs will be proofread and reviewed for compliance to 21 CFR Part 101.36, 21 CFR Part 101.9, and customer requirements.

6.1 Process for New Products

6.1.1 Label Compliance will request a sample bottle that will be used for the finished good, in order to determine label die lines. In the event that there is a secondary packaging, the sample bottle will be sent out to vendors to create carton die lines. The dimensions will be noted in the customer and product specific label folder for future use.

6.1.2 Revision control will be maintained and tracked using Ion Labs or customer printed packaging ID and revision numbers.

6.1.3 Printed packaging ID and revision numbers must be on final components to ensure proper traceability.

6.1.4 Printed packaging will be assigned an ID number by Ion Labs unless the customer has an existing ID number.

6.1.4.1 If assigned internally, the unique LPC assigned item master code or the digits of the barcode will be used as the label number. The revision

number will start at zero and will continue up sequentially when new revisions are necessary.

Example: LPC00999 R0

6.2 Supplement Facts (or equivalent) Review and Art Approval

6.2.1 For new products, Label Compliance will receive customer specific signed supplement facts (or equivalent) from R&D. This will be used to review against the formula, and check the spelling of each ingredients, as well as a regulatory review, and then sign form C-708-F1 Printed Packaging Art & Revision Approval prior to routing through R&D and Quality departments.

6.2.1.1 For reorders, Label Compliance will review the signed supplement facts from the item specific label file to ensure that no changes have been made to the formula as well as a regulatory review to ensure printed packaging compliance with the Code of Federal Regulations. If no changes are needed, complete form C-708-F1 Printed Packaging Art & Revision Approval and route through R&D and Quality departments.

6.3 Printer Proof Approval

6.3.1 Once printer proof is received, Label Compliance will review to ensure the printer proof matches the approved art on form C-708-F1 Printed Packaging Art & Revision Approval prior to routing to the Quality department using form C-708-F2 Printer Proof Comparison.

6.3.2 Once all signatures are obtained, the proof is sent to the customer for a final approval signature. Upon customer sign off, form C-708-F3 Printed Packaging Master File will be created and routed for approval.

6.3.2.1 Should a printer proof require changes, repeat steps 6.3.1 and 6.3.2.

6.4 Reorder Process

6.4.1 Using SAP, Label Compliance will verify the on-hand inventory of the printed packaging material needed to fulfill the order.

6.4.1.1 If the on-hand inventory is insufficient for the order, the existing approved printer proof will route using form C-708-F1 Art & Revision Printed Packaging Art & Revision Approval through R&D and Quality department. If no changes are needed, Label Compliance will send a PO Request to Purchasing, advising of the printed packaging ID and revision number.

Note: If no changes are needed, the customer does not need to review printer proofs for reorders.

6.5 Printed Packaging Revision Process

Note: All changes made to existing GMP documents due to label revisions will be managed following SOP C-403 Change Control Procedure.

6.5.1 Label revisions are to be tracked starting at zero. If changes are made to a previously made printed packaging material, the revision number will change accordingly.

6.5.2 Label Compliance will pull the last approved printer proof from the product file and complete the Art & Revision Approval Checklist.

6.5.3 Label Compliance, R&D, & Quality will review and approve the proposed changes. Once approved, these changes will be communicated to the customer to update the printed packaging, or will send to printed packaging vendor to make updates in the event the customer is unable to edit the art files. Revised art will then be sent back to Label Compliance.

6.5.4 Following the procedure outlined in Section 6.2, the revised art will be reviewed and approved.

6.5.5 The completed form C-708-F1 Printed Packaging Art & Revision Approval will be filed with the associated form C-708-F2 Printer Proof Comparison for the newly revised printed packaging component.

6.5.6 A new form C-708-F3 Printed Packaging Master File will be created, using the approved printer proof. When the physical printed packaging component arrives at the facility, it will be reviewed against and added to the associated printed packaging master file.

6.5.7 The printed packaging master file for the previous revision will be marked as obsolete once the new printed packaging master file has been approved. The obsolete files will be maintained in the MBR located in Document Control.

6.5.7.1 In some cases, a customer may choose to use the remainder of the obsolete revision before moving to the new revision. In these cases, a note will be made in the packaging profile that gives instruction to consume the old revision before changing to the new.

6.5.8 Obsolete printed packaging component inventory will be destroyed following SOP E-801 Return of Materials and Destruction of Non-Hazardous Waste Materials.

6.6 Printed Packaging Receiving Inspections

6.6.1 When a new shipment of a printed packaging component arrives at the facility, it will be assigned an R Number per SOP E-204 Receiving Process for Raw Materials and Packaging Components.

6.6.2 Once received, the printed packaging component will be sampled as outlined below, or in accordance with E-704 and C-708-F5, Printed Packaging Receiving Inspection – Extended Criteria, when additional inspection criteria are specified. The samples will then be delivered to Label Compliance for inspection.

6.6.2.1 For labels, cartons, shrink sleeves, and inserts, ten pieces will be submitted.

6.6.2.2 For display trays, one piece will be submitted.

6.6.3 Using form C-708-F4 Printed Packaging Receiving Inspection, the samples will be reviewed by Label Compliance and Quality for accuracy. In cases where standard procedures are deemed insufficient, form C-708-F5, Printed Packaging Receiving Inspection – Extended Criteria, will be used to satisfy the additional requirements outlined by the AQL Statistical Sampling Plan for the minor inspection level.

6.6.4 Once approved, the printed packaging component will be released in SAP.

6.6.5 All completed printed packaging receiving inspections will be kept in the label compliance file for the associated product.

6.7 Printed Packaging Inventory Control

6.7.1 All printed packaging inventory will be maintained following SOP E-101 Warehouse and Inventory Control.

6.8 Document Management

6.8.1 All label compliance documents will be managed following SOP C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	09/16/10	New procedure.	N/A	S. Shoaf
1	01/07/11	Updated SOP format.	N/A	S. Shoaf
2	02/01/11	Organized and clarified SOP.	N/A	S. Shoaf
3	02/20/13	Updated to comply with new label creation and inventory process, updated 6 forms and added 2 new forms.	13-101	S. Barbury
4	09/27/13	Updated, streamlined responsibilities, changed forms.	13-781	J. Hancock
5	09/03/14	Updated SOP and forms to new format. Referenced new packaging types, allowed for weight for powders. Updated label number section. Clarified label destruction process. Defined label size determination process. Referenced updated labeling record and blister record forms, as well as E-801 Non-Hazardous Waste Forms. Removed master label number log.	14-0373	K. Burris
6	11/16/16	Revised SOP to reflect current and applicable practices.	16-0856	R. Winger

		Removed form C-708-F1 and added form C-708-F2. Removed form C-708-F7.		
7	06/09/17	Added calibration requirements for label counter.	17-0658	S. Millar
8	07/29/20	Procedure rewrite. Removed inventory management requirements. Changed label lot number requirements. Removed form C-708-F6. Changed SOP title.	CC-20-0531	K. Burris
9	09/26/22	Updated to reflect changes in process flow, removing R&D from various parts of the process. Revised all associated forms. Changed SOP title. Changed Label Control to Label Compliance and label to printed packaging throughout SOP.	CC-22-0387	K. Burris
10	04/09/25	Updated to reflect changes in process flow added updated C-708-F4 receiving inspection form with updated SAP verification and corrected formatting. Updated sampling and review instructions to incorporate added form, C-708-F5, extended criteria receiving inspection form. Updated company logo.	CC-25-0174	J. Kiger