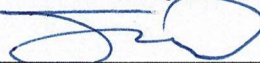

	Standard Operating Procedure Issuance of Master Case Labels		SOP Number B-112	Revision 5
			Effective Date 04/13/23	Page Page 1 of 4
Written by/ Date <i>K. Burns 10/17/22</i>	Reviewed by/ Date  10/17/22	Approved by/ Date  10-17-22		
Title: Quality Assurance Director	Title: Production Manager	Title: VP of Quality & Regulatory Affairs		

1.0 Purpose

The purpose of this procedure is to describe the steps for developing and issuing shipper labels for Production Packaging Departments.

2.0 Scope

This procedure applies to all bulk and packaged master case labels in use at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of Label Control to create “master” master case label templates when a new product is onboarded. This file is specific to a product but not to a particular batch.
- 3.2 It is the responsibility of QC to generate a batch specific master case label and/or pallet label template. QC is also responsible for reviewing and approving the template prior to making it available for use by Production.
- 3.3 It is the responsibility of Production personnel to print the required amount of labels needed for the current job, during room startup activities.

4.0 Definitions

- 4.1 **BPR** – Batch Production Record
- 4.2 **QC** – Quality Control

5.0 References

- 5.1 B-112-F1, Form, Master Case Label Request Form

6.0 Procedure

- 6.1 Creating a Master Case Label master file

- 6.1.1 When a new product is onboarded, Label Control will create a master file for the master case label, using information provided from the onboarding documents and sales order. If the master case label is to be customer specific, the master file will

file will be sent to the customer for approval. Customer approval is not required for generic master case labels. Generic master case labels will be approved internally by Quality.

6.1.1.1 A generic master case label may contain the following information:

6.1.1.1.1 Customer name

6.1.1.1.2 Product name

6.1.1.1.3 Batch number and/or customer specific lot number

6.1.1.1.4 Quantity (number of units per master case)

6.1.1.1.5 Shelf life (expiration date, best by/before date, manufacturing date)

6.1.1.2 A customer specific master case label may contain all of the information of a generic master case label, with the addition of barcodes and/or QR codes, and any other information required by the customer (such as product SKU or PO number).

6.1.2 Once approved by the customer (or internally for generic master case labels), the master file will be saved to the following location: <\\filesrvr2016\Shared\Quality\Public\Batches\Templates\Case>, using the product SKU and product name as the file name.

6.1.2.1 If the product requires both a master case label and pallet label, the file name will include the word CASE or PALLET at the end of the naming convention.

6.1.3 An example of the master file will be provided to Production Control to add as an attachment to each packaging profile. Master case and pallet label requirements are outlined in the packaging profile created for each SKU. This document is used as a reference when approving all batch specific master case and pallet labels for use in production.

6.2 Creating a Batch Specific Master Case Label template

6.2.1 QC will review Form B-112-F1 Master Case Label Request Form in the BPR for master case label requirements before the batch begins to package.

6.2.2 When all required information is available (expiration date, Julian lot number, etc.), the QC inspector will generate a batch specific master case label, utilizing

the master file provided by Label Control, and adding any necessary batch specific information required by the master file. The packaging profile may be referenced when creating the batch specific master case label template.

6.2.3 The QC inspector that created the batch specific master case label template will print one label and attach it to the back of Form B-112-F1 Master Case Label Request Form. The QC inspector will sign the Submitted By QC/Date portion of the Master Case Label Request Form and submit the form to another QC inspector to be reviewed for accuracy.

6.2.4 The reviewing QC inspector will compare the batch specific master case label template with the packaging profile and Master Case Label Request Form, ensuring that all information is complete and correct.

6.2.4.1 If the master case label template requires correction, the label will be lined through and returned to the initiator for correction.

6.2.5 Once reviewed and approved, the reviewer will sign the master case label template on the back of Form B-112-F1 Master Case Label Request Form and return the form to the initiating QC inspector.

6.2.6 The initiating QC inspector will convert the file to a PDF and save it, with the batch number as file name, to the following location:
<\\filesrvr2016\Shared\Quality\Public\Batches\Shipper> Labels.

6.3 Printing Batch Specific Master Case Labels

6.3.1 During room startup activities, the production operator will access the required batch specific master case label file by searching for the base batch number of the product that the room is being set up for.

6.3.2 The operator will print one label and affix it to the back of the packaging startup page, and add initial/date. A QC inspector will review the attached label against the BPR to ensure that the correct file has been accessed. If the file is correct, the QC inspector will initial/date below the operator's entry.

6.3.3 Once approved, the operator will sign the Labels Printed By/Date portion of Form B-112-F1 Maser Case Label Request Form and may print the quantity of labels required per the form.

6.3.3.1 All labels remaining at the end of the production run will be defaced and discarded.

6.4 Documentation Requirements

6.4.1 All Master Case Label Request Forms will be filed in the associated BPR and maintained per SOP C-502 Record Storage, Retention, and Destruction.

6.4.2 Batch specific master case label templates will be auto-archived every six months.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	10/04/12	New	12-153	M. Wienke
2	11/03/14	Biennial review	14-0867	M. Wienke
3	06/06/17	Biennial review: added section for labels generated in BarTender.	17-0655	R. Winger
4	10/19/20	Scheduled review: updated titles and made content current. Changed SOP title.	CC-20-0727	K. Burris
5	09/23/22	Updated to reflect change in responsibilities. Revised to entire process to match new process flow.	CC-22-0385	K. Burris