Written by/ Date	Reviewed by/ Date	Approved by/ Date
02/02/23	JM 02/09/23	02-09-23
Title: Quality Assurance Director	Title: R&D Manager	Title: VP of Quality & Regulatory Affairs

1.0 Purpose

The purpose of this procedure is to define the process for developing new products and adding them to the Approved Product List.

2.0 Scope

This procedure applies to all products that are manufactured and/or packaged by Ion Labs, Inc.

3.0 Responsibility

3.1 It is the joint responsibility of Management to ensure that this procedure is followed for all new products.

3.2 It is the responsibility of Document Control to maintain the Approved Product List.

3.3 It is the responsibility of R&D Management to ensure that product development activities are sufficient to ensure that the product meets the intended specifications and is able to be processed.

3.4 It is the responsibility of Maintenance & Engineering Management to ensure that the product is able to be processed on available equipment and that the equipment is in working condition.

3.5 It is the responsibility of QC Laboratory Management to confirm finished product and stability testing.

3.6 It is the responsibility of Safety Management to ensure that new products are safe for manufacture and that proper PPE and guidance is provided prior to production.

3.7 It is the responsibility of the Material Review Board members to ensure that the product is suitable for manufacturing and meets FDA requirements based on all available information.

4.0 Definitions

4.1 **Batchmaster** – ERP Software in use at Ion Labs, Inc.

4.2 **ERP** – Enterprise Resource Planning

4.3 **Shall** – Compulsory, necessitated by this procedure

4.4 **Should** – Recommended; generally standard but no compulsory

4.5 **Approved Product List** – a list comprised of all currently approved products

4.6 **Product Profile** – a document that establishes a product's raw materials, in-process specifications (critical control points), finished product specifications, and stability requirements, which ensure the identity, purity, strength, and composition of the product

4.7 **QC** – Quality Control

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

5.0 References

5.1 D-901, SOP, Raw Material Life Cycle and COA Challenge Process

5.2 C-202, SOP, Material Review Board

5.3 E-601, SOP, Vendor Qualification

5.4 C-105, SOP, Protocol and Report Documentation Requirements

5.5 G-103, SOP, Qualification of Equipment

5.6 C-601-F1, Form, New Product Approval Form

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

5.8 United States Pharmacopeia, Regulation

5.9 Food Chemical Codex, Regulation

6.0 Procedure

6.1 Sales Order SKU Codification

6.1.1 In order for a sales order of a new SKU to be generated and issued for general circulation, the SKU must be codified. The initial sales order shall reference the relevant project ID, project ID revision, and formula revision, to ensure continuity between the hypothetical formulation quoted and the finished good intended to be developed.

6.1.2 SKU codification shall utilize the following criteria:

6.1.2.1 First letter:

6.1.2.1.1 C = Cosmetic

6.1.2.1.2 P = Pet or Other

6.1.2.1.3 S = Supplement

6.1.2.1.4 D = Drug

6.1.2.2 Second two letters:

6.1.2.2.1 TB = Tablet

6.1.2.2.2 CT = Coated Tablet

6.1.2.2.3 EC = Hard-Shell Capsule

6.1.2.2.4 LS = Liquid

6.1.2.2.5 LC = Liquid Capsule

6.1.2.2.6 PW = Powder

6.1.2.2.7 GM – Gummy / Chewable Gel

6.1.2.3 The next five numerals are sequential, dependent upon the product type (cosmetic, pet, supplement, drug)

6.1.2.4 Suffix;

6.1.2.4.1 FG = Finished Good

6.1.2.4.2 PP = Pre-Pack

6.1.2.4.3 B = Blend

6.1.2.4.4 TB = Tablet

6.1.2.4.5 CT = Coated Tablet

6.1.2.4.6 EN – Capsule

6.1.2.5 X####:

6.1.2.5.1 Formula unit doses per unit of finished good product

Example:

Product Type	Product Form	Formula Number	Intermediate Type	Count
S	**CT**	54321	**FG**	**X**0240

6.2 Upon receipt of a sales order for a new product, R&D begins the product development process by planning product formulation development testing and requesting samples.

6.3 Product Development

6.3.1 R&D conducts testing necessary to meet customer requirements specified in the sales order and derives a finalized formulation and proposes a general manufacturing process.

6.3.2 R&D inputs the final formula into Batchmaster Physical Property Analysis under the codified formulation section of the finished good SKU. The formula is converted to development and activated so a bill of materials may be generated.

6.3.3 R&D generates a final Supplement Facts, Nutrition Facts, Drug Facts, or Cosmetic Ingredient Listing for the desired packaging count and serving size detailed in the sales order. The supplement facts will be approved by R&D and Quality Assurance. A copy of the panel will be provided to Label Control once approved.

6.3.4 R&D generates a product development report. This report shall comprise of at least the following sections:

6.3.4.1 Objective – Outlines the reason for the product development report; Examples include onboarding an existing product, developing a new product, redeveloping an existing product, etc.

6.3.4.2 Formulation – Weight/Dose and Weigh/Weight formula as input into Batchmaster

6.3.4.3 Details – Product form, tooling, capsule size, density, etc.

6.3.4.4 Ingredient Details / Material Specifications – Identifies and specifies all new material codes and any critical material specifications of existing raw material codes

6.3.4.5 Product Feasibility Testing – Combines the methods and results used to derive the final formula

6.3.4.6 Manufacturing Recommendations – Describes the general manufacturing process the formula is intended to follow along with any necessary/critical limits such as climate control within the manufacturing suite

6.3.5 R&D generates a draft Product Profile.

6.4 New Product Approval

6.4.1 R&D initiates a New Product Approval form, compiles it with the Product Development Report, Draft Product Profile, and any ancillary information, and routes for review and subsequent approval.

6.4.2 The QC Director or designee reviews the compiled New Product Approval information and may make changes or suggestions to test methods or otherwise by redlining the draft product profile. Upon signage, the QC Director or designee agrees that they have been informed of the necessary information regarding the new product to be approved and the specifications (material and finished good) are anticipated to be adequate for producing a product which meets all necessary label claims for the duration of the intended shelf life.

Note: In the event that the QC Director is unavailable within the time constraints necessary for sales order delivery, the allowed designees are QC Laboratory Management.

6.4.3 The R&D Manager or designee reviews the compiled New Product Approval information and may make changes by redlining the draft product profile or suggest additional testing/scale up be completed. The R&D Manager may generate a product synopsis to add to the compiled information as needed.

Note: In the event that the R&D Manager is unavailable within the time constraints necessary for sales order delivery, the allowed designee is a Senior Scientist.

6.4.4 A New Product Development Meeting will be scheduled to discuss any potential issues with the new product. This meeting should consist of Operations, Purchasing, QC, QA, Label Control, R&D, and Sales. Additional attendees may be added as needed.

6.4.5 The NPA packet will be updated with any changes needed from the New Product Development Meeting. Once complete, the NPA packet is sent for approval by the Material Review Board. The Material Review Board consists of the Vice President of Operations, Production Director or Manager, Maintenance and Engineering Manager, Vice President of Quality and Regulatory Affairs, Quality Assurance Director, Quality Control Director, R&D Manager, and CEO. As outlined in SOP C-202 Material Review Board, only three members of the MRB are needed to approve a new product.

6.4.6 The NPA packet will be reviewed by Safety Management or designee to ensure that all safety precautions are addressed during product creation.

6.4.7 Upon approved by the Material Review Board and Safety, the New Product Approval form with all compiled information shall be delivered to Document Control, who will then add the approved product to the Approved Product List, maintain a record of the compiled information, and notify Sales that the product has been approved for manufacture. The New Product Approval and compiled information shall be made available to Sales. Sales should review and sign the New Product Approval Form.

6.4.8 Once a product is approved for manufacturing, the Bill of Materials may be built and/or activated and a batch cut may be issued to generate raw material demand.

6.4.9 Completed NPA packets will be scanned and filed here: U:\Quality\Private\Doc Control\Forms and Logs\New Product Approvals\NPAs. The scanned packet should include all redlines and notes that were compiled during the New Product Development Meeting or during document routing.

6.4.10 Once scanned and filed electronically, the physical packet will be sent back to the Formulation Scientist so that the Product Profile can be updated and submitted to Document Control to begin the approval process.

6.5 Documentation Maintenance

6.5.1 All documents shall be maintained as outlined in SOP C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	05/15/13	New procedure.	13-388	C. Desjardine
2	07/22/13	Removed RMTC in section 5.5.5. Added section 5.1.7. Added formula number and table for signoff from management committee members.	13-466	V. Iltcheva
3	09/03/13	Added definitions for product profile, new product approval report, and new product design notebook. Added section 5.1.3.1 and 5.1.3.2 to address use of design notebook and approval report. 5.1.7 Add supplement facts to product profile. 5.2.1 Change the requested RMSTT for new raw materials.	13-780	L. Titolo
4	10/09/13	Replaced Management Committee with MRB. Removed section 5.3.2.	13-871	V. Iltcheva
5	12/23/14	Changed responsibilities. Removed new product design notebook reference. Added that all testing will be documented in the NPA. Updated format. Generalized to include OTC.	14-1028	L. Titolo
6	01/13/16	Remove manual hardcopy log; maintain electronic log.	16-0083	D. Popp
7	11/28/16	Added more detail about sections of NPA specific requirements for dietary supplements, Cosmetics and OTC and reorganization for clarity.	16-1064	L. Titolo
8	11/10/21	Complete re-write to suit the actual process evolved from company growth and implementation of Batchmaster ERP system.	CC-21-0416	C. Fryman
9	02/02/23	Changed product review board to material review board. Changed file path for completed scanned NPA packets. Changed responsibilities section. Added reference to C-202 Material Review Board SOP. Added AD and FPTD. Added Safety. Updated form.	CC-23-0063	K. Burris

ION LABS	New Product Approval Form		
	Form: C-601-F1	CCR No. CC-23-0063	Revision: 8

SECTION 1 - INITIATION

Project Number:		**Issued By / Date:**	
Product Name:			
Formula Number:			

Initiated By:		**Date:**	

Completed By:		**Date:**	

SECTION 2 - REVIEW

QC Director:		**Date:**	

R&D Manager:		**Date:**	

SECTION 3 – MATERIAL REVIEW BOARD APPROVAL*

Title	Print Name	Signature	Date
Operations Management			
Maintenance Management			
Safety Management			
R&D Management			
Quality Management			

** At least three MRB members must give approval.*

SECTION 4 – SAFETY APPROVAL

Title	Print Name	Signature	Date
Safety Management			

SECTION 4 – COMPLETION

Approval Status:	☐ Approved ☐ Rejected ☐ Other _____
Product Added to APL:	☐ Yes ☐ No (If no, provide reason: _____)

Completed By

Quality Systems:		**Date:**	

Acknowledged By

Account Manager:		**Date:**	