<table>
<tr><td rowspan="2">ION LABS</td><td rowspan="2">Standard Operating Procedure

New Product Realization Process</td><td>SOP Number
C-603</td><td>Revision
2</td></tr>
<tr><td>Effective Date
02/14/22</td><td>Page
Page 1 of 7</td></tr>
<tr><td colspan="2">Written by/ Date
02/15/22</td><td colspan="2">Reviewed by/ Date
02/15/22</td><td>Approved by/ Date
02/15/22</td></tr>
<tr><td colspan="2">Title: R&D Manager</td><td colspan="2">Title: Product Development & Engineering Director</td><td>Title: Quality Systems Manager</td></tr>
</table>

1.0 Purpose

The purpose of this procedure is to define the new product realization process to ensure consistent processes are followed when establishing a new dietary supplement, OTC, cosmetic, or pet product.

2.0 Scope

This procedure applies to all new dietary supplements, OTC, pet products, and cosmetics that are to be manufactured by Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of the R&D Manager or designee to ensure that this procedure is followed during the development of new dietary supplements, OTC, cosmetics, pet products.

3.2 It is the responsibility of R&D to follow this procedure.

3.3 It is the responsibility of QC Laboratory personnel, in conjunction with R&D, to define all finished product and stability testing, as well as any test exemptions.

4.0 Definitions

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

4.2 **DC** – Document Control

4.3 **QC** – Quality Control

4.4 **NPA** – A document consisting the products components, formulation details, product

feasibility testing including, assessments, evaluations, product validation protocols, process validation protocols, product specifications, and as needed equipment IQ, OQ, and Cleaning Validation protocols.

4.5 **APL** – Approved Product List; list of all approved dietary supplements, OTC products, pet products, and cosmetics

4.6 **Product Profile** – A document that establishes a product's components, in-process specifications (control points – CCP), finished product specifications, and stability requirements which ensures the identity, purity, strength, and composition of the product.

4.7 **CCP** – Critical Control Point

4.8 **OTC** – Over the Counter

5.0 References

5.1 A-116, SOP, Ensuring the Identity, Purity, Strength and Composition of Dietary Supplements

5.2 A-119, SOP, Ensuring the Identity, Purity, Strength and Composition of Liquid Form Finished Products

5.3 A-106, SOP, Documentation Guidelines for cGMP Records

5.4 C-605, SOP, New Product Quotation Process

5.5 C-403, SOP, Change Control Procedure

5.6 C-601, SOP, New Product Approval Process

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

5.8 D-401, SOP, New Product Documentation Requirements

5.9 D-401-F2, Form, Finished Product Test Ticket

6.0 Procedure

6.1 Costing is completed following the quotation process described in SOP C-605 New Product Quotation Process.

6.2 Customer is provided with price quote.

6.3 The customer places an order for the new product which initiates the drafting of the NPA and Product Profile by R&D.

6.4 R&D must ensure that they have all of the necessary documents from the original quote to guarantee that all customer requirements for the formulation are met.

6.5 R&D will evaluate the formulation and conduct fundamental functionality testing to assess the formulation. This may include but not be limited to the following:

6.5.1 Dietary Supplements

6.5.1.1 Density

6.5.1.2 Capsule Fill

6.5.1.3 Viscosity

6.5.1.4 Compression

6.5.1.5 Flow Properties

6.5.1.6 Particle Size

6.5.1.7 Raw Material Assessment

6.5.2 OTC

6.5.2.1 Raw Material Assessment

6.5.2.2 Product feasibility

6.5.2.2.1 Density

6.5.2.2.2 Capsule Fill

6.5.2.2.3 Viscosity

6.5.2.2.4 Compression

6.5.2.2.5 Flow Properties

6.5.2.2.6 Particle Size

6.5.2.3 Process Validation Protocol

6.5.2.4 Stability Protocol

6.5.2.5 Cleaning Validation Protocol

6.6 Following SOP C-601 New Product Approval Process, R&D will complete Form C-601-F1 New Product Approval Form and prepare the NPA report. The report will cover the following areas:

6.6.1 Objective

6.6.2 Formulation

6.6.2.1 For Dietary Supplements: Activity and overages of each active ingredient and a list of inactive ingredients

6.6.2.2 For Cosmetics: the product components, including the INCI nomenclature and label listing

6.6.2.3 For OTC: components, formulation including critical raw material specifications and warnings (CAS, grade, descriptions)

6.6.2.4 For Pet Products: Activity and overages of each active ingredient and a list of inactive ingredients

6.6.3 Details – on the appearance

6.6.3.1 Form – liquid, solid dose, powder, cream

6.6.3.2 Appearance – shape, size, color, flavor

6.6.4 New Raw Materials to be approved

6.6.4.1 Formulas which utilize all approved materials will simply state that all raw materials are approved.

6.6.4.2 Products for which one or more materials are not on the Approved Product Material List.

6.6.4.3 This list will be sent to the QC Laboratory Director and designated personnel to obtain standards.

6.6.5 Process Testing - details of testing conducted that ensures the ability to successfully process a new product

6.6.5.1 For Dietary Supplements: feasibility testing and process evaluation testing

6.6.5.2 For Cosmetics: feasibility testing and process evaluation testing

6.6.5.3 For OTC product feasibility testing including, assessments, evaluations, product validation protocols, process validation protocols, and as needed equipment IQ, OQ, and Cleaning Validation protocols

6.6.5.4 For Pet Products: feasibility testing and process evaluation testing

6.6.6 Manufacturing Concerns

6.6.6.1 Raw material handling considerations

6.6.6.2 Manufacturing equipment considerations and recommendations

6.7 After the NPA has been approved, R&D will create a product profile and submit it to DC.

6.7.1 The product profile will contain the following information:

6.7.1.1 Product Description

6.7.1.2 Formula, which will include:

6.7.1.2.1 Target or Label Claim

6.7.1.2.2 Activity of Raw Materials

6.7.1.2.3 Overages for Active Materials

6.7.1.2.4 Unit Dose

6.7.1.3 Unit Dose Supplement Facts and required label information relating to the formula

6.7.1.4 Manufacturing Section, which will include all in-process tests used to evaluate the manufacturing process during CCP

6.7.1.5 Finished Product Testing

6.7.1.5.1 Identity

6.7.1.5.2 Strength per Unit Dose

6.7.1.5.3 Composition

6.7.1.5.4 Purity

6.7.1.5.5 Heavy Metals (as needed)

6.7.1.6 Test Exemptions

6.7.1.7 Stability Testing (as needed)

6.7.2 Form D-401-F2-XXXXXXX Finished Product Test Ticket will be created which reflects the finished product release testing requirements as outlined in

the product profile. This will be the document that final test results will be recorded on during batch release activities.

6.7.3 As raw materials are procured, R&D will evaluate and approve each raw material for the new product by conducting a campaign review.

6.7.4 R&D will conduct a lab scale and production pilot batch as needed.

6.7.5 R&D will continue to monitor the process and product throughout the product's life cycle through Campaign Reviews.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	01/05/15	New	14-1022	L. Titolo
1	11/29/16	Updated document for clarity on NPA section and product mix	16-1061	L. Titolo
2	01/31/22	Modified to reflect current practices.	CC-22-0045	J. Humphrey