1.0 Purpose

The purpose of this procedure is to provide a uniform method of receiving, documenting, evaluating, reporting and investigating complaints in a timely manner. It is intended to ensure compliance to FDA Dietary Supplement and Nonprescription Drug Consumer Protection Act and 21 CFR Part 111 Subpart O, 21 CFR Part 211 Subpart J and 21 CFR Part 117 Subpart G.

2.0 Scope

This procedure is applicable to any product sold, manufactured or distributed by Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Quality Management or designee to implement and maintain this procedure.

3.2 It is the responsibility of QA to ensure each complaint is logged, acknowledged, investigated, and corrective/preventive action is implemented and closed per this procedure.

3.3 Personnel who may interact with a customer or may receive a complaint are trained on this procedure.

3.4 Any person receiving information from a customer or product user that meets the definition of a complaint is responsible for complying with this procedure.

4.0 Definitions

4.1 **Adverse Event** – any health-related event associated with the use of a dietary

supplement, cosmetic or OTC that is adverse

4.2 **Product complaint** – any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a dietary supplement, OTC or cosmetic that could be related to current good manufacturing practice. Examples: Foul odor, off taste, illness or injury, skin irritation, disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a container, supplier issue, improper packaging, mislabeling, or dietary supplements or OTC that are superpotent, subpotent, or contain the wrong ingredient, or contain a drug or other contaminant (e.g., bacteria, pesticide, mycotoxin, glass, lead).

4.3 **RPAN** – Returned Product Authorization Number

4.4 **Serious Adverse Event** – any event resulting in a death, life-threatening experience, in-patient hospitalization, a persistent or significant disability or incapacity or congenital anomaly or birth defect or requires, based on a reasonable medical judgment -a medical or surgical intervention to prevent the outcome as described above

4.5 **OTC** – Over the Counter; Drugs that have been found to be safe and appropriate for use without the supervision of a health care professional such as a physician, and they can be purchased by consumers without a prescription

4.6 **Cosmetic** – Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body, for cleaning, beautifying, promoting attractiveness, or altering the appearance (FD&C Act, sec. 201(1)

4.7 **QA** – Quality Assurance

4.8 **COMP number**– traceable number provided for each complaint issue

4.9 **DC** – Document Control

4.10 **CAPA** – Corrective and Preventative action

5.0 References

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

5.2 E-501, SOP, Procedure for Returned Products

5.3 QS-101-F1, Form, Complaint Report Form

5.4 QS-102, SOP, Adverse Events

5.5 QS-108, SOP, Corrective and Preventive Action (CAPA)

5.6 QS-112, SOP, Core Quality Systems and Quality Events

5.7 QS-112-F1, Form, Quality Event Extension Request

5.8 Health Canada - Canada Consumer Products Safety Act (Section 14) and the Food and Drug Act

6.0 Overview

6.1 Complaints are one of a number of quality systems governed by SOP QS-112 Core Quality Systems and Quality Events. SOP QS-112 Core Quality Systems and Quality Events manages the following aspects of all quality events:

6.1.1 Assignment of unique event numbers

6.1.2 Logging of events with DC

6.1.3 Assignment of event due dates

6.1.4 Event due date extensions

6.1.5 Event cancellations

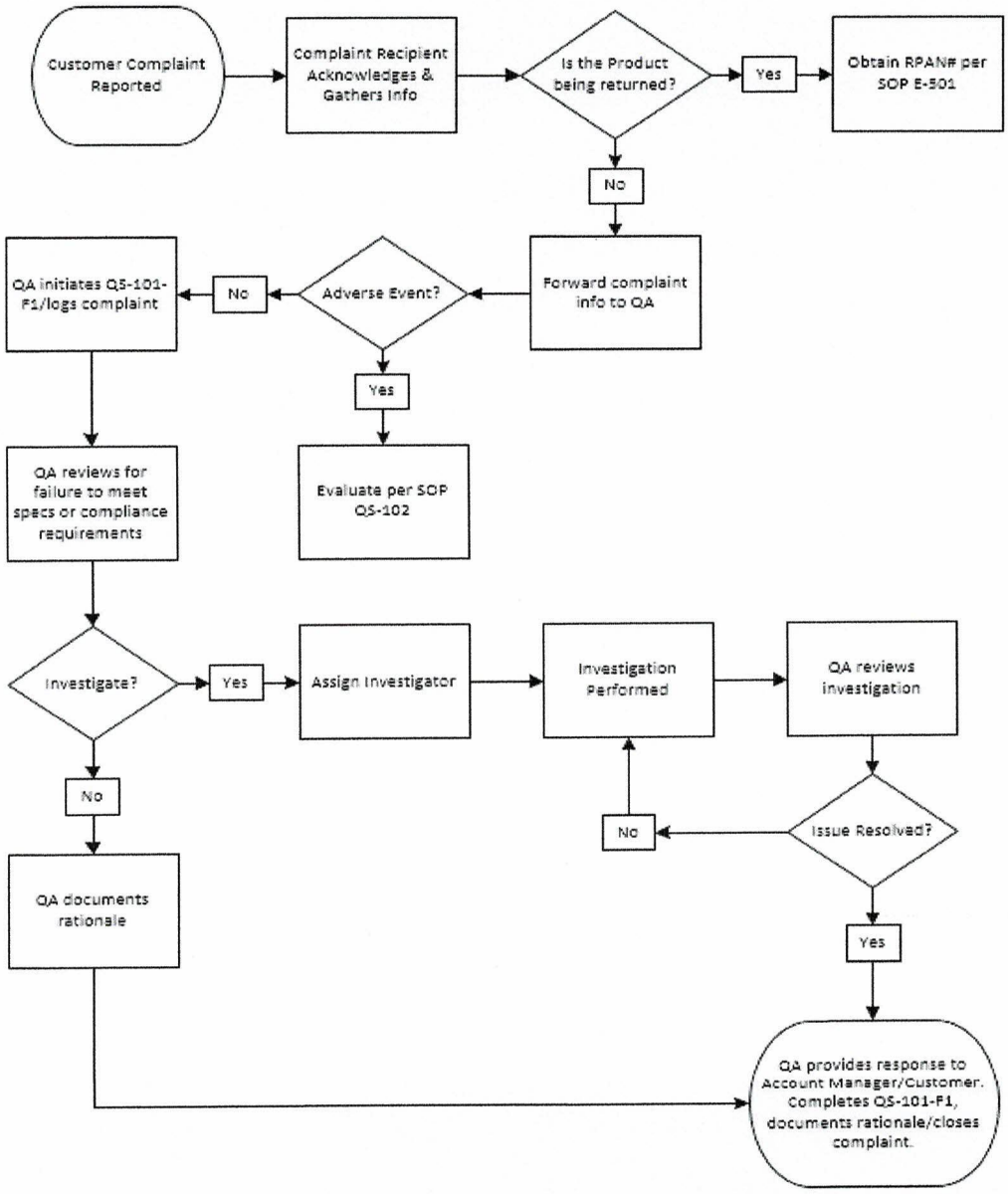
6.1.6 Monitoring of open events

6.1.7 Record retention instructions

7.0 General Requirements

7.1 All complaints are processed in accordance with the flow chart in Figure 1.

Figure 1



8.0 Complaint Handling

8.1 Complaint recipient will acknowledge and gather complaint information.

8.2 Complaint information will be provided to QA by email, but **no later than one business day** from receipt of complaint. A reason is required if complaint is not provided as expected.

8.3 At a minimum, the following complaint information is needed:

8.3.1 Mode of receipt

8.3.2 Date and time of complaint

8.3.3 Name of complainant/Company

8.3.4 Phone number of complainant

8.3.5 Product name and formula identification number

8.3.6 Batch number

8.3.7 Brief description of the alleged product problem

8.3.8 Is the complaint product being returned?

8.4 If the information received alleges an adverse event, the following information **must be** obtained (if available):

8.4.1 The patient or product user's name affected by the adverse event

8.4.2 The name of the person that initially reported the event (user, doctor, etc.)

8.4.3 Identity and contact information for the responsible person, if other than Ion Labs (i.e., the manufacturer, packer, or distributor)

8.4.4 A description of the serious adverse event

8.5 If the customer is requesting to return the product, follow SOP E-501 Procedure for Returned Products. Provide the RPAN to the customer to reference on incoming paperwork (if possible).

8.5.1 Returned product will be evaluated for defect(s) as it pertains to the complaint. This may require one or more of the following steps:

8.5.1.1 Examination of product for conformance to finished specifications.

8.5.1.2 A review of historical records (i.e. lot production/batch records) to identify anomalies or errors relevant to the complaint.

8.5.2 The analysis for the product may be reviewed (when applicable) to determine whether a new hazard has been identified.

8.6 If a customer is returning one or a few complaint bottles, it will be documented on QS-101-F1 Complaint Report Form. No RPAN will be necessary unless circumstances change.

8.7 In the event that the physical product was not returned with the complaint, it will be clearly indicated.

8.7.1 In such case, the investigator may review historical records (i.e. lot production, batch records, reserve samples) to identify anomalies or errors relevant to the complaint.

8.8 Where a complaint represents an adverse event, the complaint is promptly reviewed, evaluated, and reported as per SOP QS-102 Adverse Events, when required.

9.0 Complaint Processing

9.1 QA will complete Section 1 of form QS-101-F1 Complaint Report Form, documenting as much information as is available regarding the details of the product deficiency or user

experience. All initial and continual correspondence should be recorded here and documented appropriately.

9.2 If the complainant provides their company complaint report form or other document, that assigned number will be added to form QS-101-F1 Complaint Report Form, under the complaint description.

9.3 QA will request a COMP number from Document Control for each complaint issue, whether it is for a complaint category or batch number. For example:

9.3.1 Customer complaint for broken tablet and no seal for same batch. DC will assign two separate COMP numbers:

9.3.1.1 Broken Tablet

9.3.1.2 No Seal

9.3.2 Customer complaint for broken tablet and no seal, same issues but for two batches. DC will assign four COMP numbers:

9.3.2.1 Broken tablet for Batch 1

9.3.2.2 Broken seal for Batch 1

9.3.2.3 Broken tablet for Batch 2

9.3.2.4 Broken seal for Batch 2

9.4 DC will maintain a log of each COMP number per SOP QS-112.

9.5 Complaints are processed in a timely manner, with a goal of 45 business days to closure (includes notification to customer, if required). Should closure exceed 45 business days, a CAPA may be initiated following SOP QS-108 Corrective and Preventative Action, at the discretion of the Senior Quality Management. The customer is to be notified of the extension and reason.

10.0 Complaint Evaluation

10.1 Upon confirmation of a product failure (including packaging) to meet any of its specifications or compliance with 21 CFR 111, 21 CFR 211 or 21 CFR 117 (applicable sections), an investigation must be performed.

10.2 A new investigation may not be necessary for a dietary supplement type product if a previous investigation was performed for the same batch number and reported deficiency; the root cause must have been identified and corrective and preventive actions implemented, if required. A reference to the complaint report containing the previous investigation is referenced as well as a documented rationale for applicability.

10.3 All OTC/cosmetic product complaints will be investigated, regardless of previous investigation. Reference to the similar previous complaint report containing the previous investigation will be made in the respective complaint file.

10.4 If required, QA will assign an investigator based on the complaint category.

10.5 Investigation activities may include:

10.5.1 An evaluation of the complaint sample and reserve sample, if available.

10.5.2 Review of relevant documentation such as batch records, equipment logbooks, personnel training records, trends, etc.

10.5.3 Impact assessment to determine if the issue affects other batches, lots, etc.

10.5.4 Assess impact on product quality and whether it might be attributable to the cause of the complaint.

10.5.5 Testing of the complaint sample and associated batch retained sample are performed per approved procedures, as applicable to the reported issue.

10.6 Investigation details and any evidence, including test results, are attached form QS-101-F1 Complaint Report Form.

11.0 Complaint Report and Closure

11.1 A decision is made as to whether corrective action is required, consulting with other functions as needed. If a CAPA has already been initiated for the issue, the CAPA number is referenced on the Complaint Report. A rationale is documented on the Complaint Report if a CAPA is not issued.

11.2 QA will review the investigation details and a complaint response is prepared. The response should include specific details of the investigation including any corrective and preventative action take and a root cause, as applicable.

11.3 A final review of the complaint is performed to ensure all requirements are met. Upon final review and closure, QA management may recommend additional corrective actions based on an assessment of the nature, frequency, and severity of the complaint, the presence of a confirmed defect or failure, and the potential for replication of a product defect or failure, which may lead to injury. Corrective action taken may include one or more of the following actions:

11.3.1 Training/Retraining

11.3.2 Modifications of procedures and/or equipment

11.3.3 Field correction or recall

11.3.4 Institution of a task force to study problems requiring long term analysis and corrective action

11.3.5 Update to the risk analysis for new hazard(s) identified by the complaint

11.4 The complaint response is signed by QA and then either forwarded to the assigned account manager to send to the customer or sent to the Quality contact of the company. If the complainant provided their complaint report form to be completed, it must be filled out appropriately and returned.

11.5 Multiple complaint issues (COMPs) may be addressed in a Complaint Response. The complaint is closed once the letter has been provided. Complaints are traced by Closed/Report Dates.

11.6 Form QS-101-F1 Complaint Report Form is completed and reviewed/approved by QA Management.

11.7 If the decision is made to replace the product, a copy of form QS-101-F1 Complaint Report Form is submitted to Accounting for account adjustment and customer notification.

11.8 Trending reports will be provided for Management Review.

12.0 Records

12.1 Complaint reports associated with adverse events are maintained at least six years, as outlined in SOP C-502 Record Storage, Retention, and Destruction, regardless if the event is required to be reported to the FDA as per SOP QS-102 Adverse Events. These records should include, at a minimum, copies of the following:

12.1.1 The responsible person's serious adverse event report to FDA on MedWatch Form 3500A, with attachments.

12.1.2 Health Canada Mandatory Reporting -Canada Consumer Products Safety Act (section 14) and the Food and Drug Act (adverse reaction/event). Natural Health Products marketed in Canada are reported in the MedEffect Canada reporting system.

12.1.3 Any new medical information about the serious adverse event received by the responsible person.

12.1.4 Any reports to FDA of new medical information related to the serious adverse event.

12.1.5 Communications between the responsible person and the initial reporter, or any other person(s) who provided information related to the adverse event.

12.2 Any new medical information which is received later than one year after the serious adverse event report and therefore does not have to be reported, must be kept in the file on the serious adverse event for six (6) years because it is a record related to the serious adverse event report.

13.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	01/23/14	Replaces I-101: revised complaint number format to accommodate recent direct-to-consumer sales, implementation of tracking database, clarification of adverse event requirements, and changed primary responsibility to Director QA/RA. Revised document format.	14-0034	L. Derrick
1	05/17/14	Added steps for trending, management review, and complaint acknowledgement.	14-0405	S. Millar
2	12/03/14	Added additional information including preventive action and impact assessment, as continuous improvement measure.	14-0856	D. Popp
3	03/01/16	Revised SOP to reflect current practices and responsibilities.	15-0993	S. Millar
4	11/29/16	Add reference to OTC and cosmetic products	16-1090	S. Millar
5	05/13/19	Revised SOP to include reference to 21 CFR Part 117. Revised closure time requirements. Revised Flow to ensure event is logged. Revised Form QS-101-F1 to include reference to secondary reviewer/approver and By/Mfg regarding date associated ~~with~~ product. Removed serious adverse event detail description of event, and remove Complaint Receipt section referencing person receiving complaint.	19-0332	S. Millar
6	01/16/23	Revised entire procedure to reflect current practices. Updated logo and formatting.	CC-23-0048	C. Horelle

ION LABS	Complaint Report Form		
	Form: QS-101-F1	CCR No. CC-23-0048	Revision: 5

Complaint Number: _____

COMPLAINT RECEIPT

Mode of Receipt: ☐ Phone ☐ E-mail ☐ Letter ☐ Fax ☐ Other: _____

Name of Complainant/Company: _____ Phone No.: _____

Address: _____

Date Received: _____ Batch No.: _____ Mfg Date: _____

Product Name/Description: _____ Product Formulation: _____

Product Type (Supplement, OTC, Cosmetic): _____ Dosage/Strength: _____

Packaging Configuration: _____ Mfr: ☐ Ion Labs ☐ Other

Complaint Description:

Did an adverse event occur? ☐ No ☐ Yes, Name of Person affected: _____

If yes, initial reporter name (user, doctor, etc.): _____

If yes, and a serious adverse event occurred, provide a detailed description of the event, if provided:

Will sample be returned? ☐ No ☐ Yes (RPNA #, Other) _____ (attach final copy)

Recorded By: _____ Date: _____

CORRESPONDENCE/CONTACT LOG

Date	Person Contacted	Details	Contacted by

Complaint Number: _____

COMPLAINT CATEGORIZATION

Complaint Group & Categories

☐ **Adverse Event:**
☐ Adverse Event ☐ Adverse Event (Serious)

☐ **Foreign Material:**
☐ Identified ☐ Unidentified

☐ **Product:**
☐ Appearance ☐ Clumping/Hard ☐ Damage/Broken/Leaking ☐ Disintegration Time ☐ Odor ☐ Other ☐ Performance ☐ Size ☐ Strength ☐ Taste ☐ Unapproved Supplier ☐ Weight

☐ **Primary Package:**
☐ Appearance ☐ Damage ☐ Desiccant Problem ☐ Functionality ☐ Label Problem ☐ Missing Components ☐ Other ☐ Open Exposed Product ☐ Open Exposed Components ☐ Print Problem ☐ Quantity Wrong ☐ Seal Problem

☐ **Secondary Package:**
☐ Appearance ☐ Damage ☐ Label Problem ☐ Missing Components ☐ Open Exposed Contents ☐ Other ☐ Print Problem ☐ Quantity Wrong ☐ Seal Problem

☐ **Tertiary Package:**
☐ Appearance ☐ Damage ☐ Label Problem ☐ Missing Components ☐ Open Exposed Contents ☐ Other ☐ Print Problem ☐ Quantity Wrong ☐ Pallet Problem ☐ Seal Problem

Affects other product or batches? ☐ Yes ☐ No Explain: _____

Is investigation required? ☐ Yes ☐ No, justification: _____

_____

If yes, assigned to: _____ Due Date: _____

COMPLAINT INVESTIGATION COMPLETE/CLOSED

Conclusion: ☐ Complaint is substantiated ☐ Complaint is not substantiated

CAPA Required? ☐ No ☐ Yes: CAPA # _____

Product Replacement: ☐ No ☐ Yes

Complaint Response Completed By: _____ Closed/Report Date _____

*Attach Complaint Response and supporting documentation

FINAL REVIEW AND APPROVAL

Complaint Reviewed/Approved by: _____ Date: _____

Comments: