1.0 Purpose

The purpose of this procedure is to identify the requirements for performing a recall to remove or correct consumer products that are in violation of laws administered by the Food and Drug Administration in compliance with FDA 21 CFR Part 7, CFR Part 111, 117, 330 and 507 as applicable, as pertains to Food and Drug.

2.0 Scope

This procedure applies to all products sold or distributed to include customer direct by Ion Labs, Inc., which are determined or suspected to be in violation of applicable regulations and may pose a potential hazard to the public health. For contract-manufactured products, customers will be notified of any issues related to product safety. It is the customer's responsibility to initiate any recall activities collaborating with Ion Labs, where necessary.

3.0 Responsibility

As a registered food and drug facility through the FDA, under section 415(a) of the FD&C Act (21 U.S.C. 350d), and section 510 of the FD&C Act (21 U.S.C 360), Ion Labs acknowledges the requirement to issue a report when there is a reasonable probability that the use of, or exposure to, an Ion Labs product will cause serious adverse health consequences or death to humans or animals.

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

3.2 Importers are accountable for providing all recall information to Health Canada - referencing the Health Canada Natural Health Products Regulation SOR/2003-196

(Section 24) -Canada Vigilance online Adverse Reaction Reporting (MedEffect Canada Guidelines).

3.3 NSF/GRMA- shall be notified by a Quality Representative should any instance of a food safety incident of a public nature, or product recall be initiated within 24 hours of occurrence

3.4 NSF- shall be notified immediately in case of withdrawal or recall of a NSF Gluten-Free Certified Product.

3.5 For Nutritional Food Products, the Reportable Food Registry (RFR) requires a responsible party (recall team) to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are "Reportable Foods." A report will be filed within 24 hours after the recall team determines that the article of food is a reportable food.

4.0 Definitions

4.1 **FDA** – United States Food and Drug Administration.

4.2 **CFR** – Code of Federal Regulations

4.3 **RFR** – Reportable Food Registry

4.4 **Recall** – A firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. The recall will be planned in accordance with 21 CFR Sec. 7.40 through 7.49, 7.53 and 7.55. Sr. Management will enlist legal counsel if required.

4.5 **Market Withdrawal** – Removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of

manufacturing or distribution problems would be a market withdrawal.

4.6 **Field Corrections** – Field Corrections will be performed by the recalling firm representatives, or under their supervision and control. It is not recommended that a disinterested party such as a wholesaler or retailer be responsible for field corrections. For Drug Recalls: Misbranded drugs for re-labeling should be returned to the recalling firm

4.7 **Mock Recall** – An exercise that is performed twice a year to ensure Ion Labs' ability to test the recall process and identify the distribution location of all products of interest in the event of a finished product or raw material incident. This may include a Traceability Exercise (ref. attachment 3) which is designed to test the company's ability to trace product to the customer (up-one) and by also tracing raw materials back to the supplier (one-down). Product is chosen randomly for this exercise.

4.8 **Recalling Firm** – The firm that initiates a recall or, in the case of an FDA–requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

4.9 **Recall Strategy** – A planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

4.10 **Depth of Recall** – The recall notification should clearly identify the depth to which the recall is to extend (e.g. wholesale, retail, or user level). If the recall is to the retail level, a statement should read, "This recall is to the retail level". If product could have been further distributed by your customers, then you should include instruction to subrecall. Subrecall instructions should also include the depth of the recall (e.g. "If you have further distributed this product, you should notify your customers to the retail level." If customers are instructed to conduct subrecalls, it is advisable to provide them with the date range that the recalled product was distributed. A subrecall letter will need to accompany the notification package for or customers to further notify their sub accounts.

This will ensure that the information to the sub accounts is accurate and complete.

Note: It is not appropriate for a sales representative to visit a doctor's office or customer and remove product without notifying the responsible staff. It is also not appropriate for sales representative or broker representatives to remove product from retail shelves without informing store management of the recall. Failure to inform store management of the recall could result in product that is in storage, in transit to the store, or returned by customers, being offered for sale. There is a risk that product that is in-transit or returned to the store may be sold to the customer.

4.11 **Recall Classification** – The numerical designation, i.e., I, II, or III, assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. Refer to 21 CFR Chapter 7.1 Recalls Subchapter 7.1.1.2

4.11.1 Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death

4.11.2 Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote

4.11.3 Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences

4.12 **Recall Team** – The team will be comprised of key staff with the expertise, authority, and responsibility to manage the recall. The group will consist of (at a minimum) the CEO, the VP of Quality and Regulatory Affairs, the CFO, the Quality Assurance Director, Quality Control Director, Director of Supply Chain, and the Chief Operating Officer. The team shall be responsible for satisfying all aspects/phases of the recall. The VP of Quality and Regulatory Affairs will lead the Recall Team and process.

4.13 **Press Release** – A notice that alerts the public (including regulators, retailers, consignees, other distributors, and consumers) that a product presents a serious hazard to health. Not all recalls require a press release; the regulatory agency will advise the firm when a press release is necessary.

4.14 **Stock Recovery** – A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

4.15 **Terminated** – FDA has determined that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and proper disposition has been made according to the degree of hazard.

4.16 **NSF International** – an accredited, independent third-party certification body that tests and certifies products to verify they meet public health and safety standards; Originally established as the National Sanitation Foundation to standardize sanitation and food safety requirements. Ion Labs is certified under NSF and GRMA (Global Retailer and Manufacturer Alliance)

5.0 References

5.1 C-201, SOP, Deviation and Investigation Procedure

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

5.3 E-501, SOP, Procedure for Returned Products

5.4 QS-107-F1, Form, Recall Notification Form

5.5 FDA Title 21 CFR part 7, Enforcement Policy, Subpart C-Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities

5.6 SOR/2003-196 Natural Health Products Regulations

6.0 Recall Submission to FDA

6.1 The VP of Quality and Regulatory Affairs will notify the local FDA Recall Coordinator as soon as a decision is made that a recall is appropriate through an investigation (Refer to SOP C-201 Deviation and Investigation Procedure) and prior to the issuance of press or written notification to customers providing the minimum but not limited to the following information using Form QS-107-F1 Recall Notification Form:

6.1.1 Product information

6.1.1.1 Product name

6.1.1.2 Description of the product including its form (powder, liquid, tablets, capsule, gummies, etc.), its indication or intended use, its expected shelf life, its type of packaging (i.e. box, flexible plastic, glass)

6.1.1.3 Two complete sets of all labeling used including all private labels used for Product Labeling, individual package label, Case Label (photocopy acceptable), Package Inserts, Directions for Use and all promotional material (if applicable) must be sent to the local FDA District Recall Coordinator.

- Additional Information for Drug Recalls: NDA/ANDA/NADA Number, NDC Number, Indicate if prescription or OTC, Strength, Route of Administration (where applicable).

6.1.1.4 Production Identification Numbers

6.1.1.5 Batch number(s)

6.1.1.6 Expiration date, or Use by date, or Expected shelf life of product

6.1.1.7 Universal Product Codes (UPC)

6.1.2 Recalling firm - the following information about Ion Labs, Inc. must be provided to the local FDA Recall Coordinator.

6.1.2.1 Firm name, address, city, state, zip code

6.1.2.2 FDA registration number, if applicable

6.1.2.3 Identify firm type (i.e. manufacturer, importer, broker, repacker, own-label distributor)

6.1.2.4 Name/title/phone/fax number/e-mail address for Ion's recall contact and/or most responsible individual for the recall

6.1.3 Reason for the recall – a detailed explanation of how the product is defective and/or violative and how the defect affects the performance and safety of the product should be provided to the local FDA Recall Coordinator. The following information has to be provided, as applicable:

6.1.3.1 Description of a foreign object's size, composition, hardness, and sharpness if the recall is due to the presence of a foreign object.

6.1.3.2 Description of a contaminant (e.g. cleaning fluid, machine oil or paint vapors) and level of it in the product if the recall is due to the presence of a contaminant. Provide labeling, a list of ingredients and the Safety Data Sheet (SDS) for the contaminant.

6.1.3.3 The specifications and report of all test results if the recall is due to failure of the product to meet product specifications.

6.1.3.4 Identification of correct and incorrect label(s), description(s), and formulation(s) if the recall is due to a label/ingredient issue.

6.1.3.5 Explanation on how the problem occurred and the date it occurred.

6.1.3.6 Explanation on how the problem was discovered and the date discovered.

6.1.3.7 Explanation on whether the problem or defect affects all units subject to recall, or just a portion of the units in the lots subject to recall.

6.1.3.8 Detailed information on complaints associated with the product/problem including – date of complaint, description of complaint including details of any injury or illness, batch number.

6.1.4 Health Hazard Assessment – an assessment of the health risk associated with the problem or defect (if any) should be provided to the local FDA Recall Coordinator.

6.1.5 Volume of Recalled Product

6.1.5.1 Total quantity produced and date(s) produced

6.1.5.2 Quantity distributed and date(s) distributed

6.1.5.3 Quantity on hold by recalling firm

6.1.5.4 An estimation of the amount remaining in the marketplace

6.1.5.5 Status/disposition of marketed product

6.1.6 Distribution Pattern - the following information with respect to the distribution pattern of the recalled products will be provided to the local FDA Recall Coordinator.

6.1.6.1 The number of direct accounts that are customers to whom the recalled product was sold to directly.

6.1.6.2 Consignee list of all customers both national and foreign to whom the recalled product was sold including their names/address/city/state contact name/phone number.

6.1.6.3 This is obtained by running a report to identify all customers receiving the recalled product.

6.1.7 Recall Strategy

6.1.7.1 Indication of the level in the distribution chain to which the recall will be extended

6.1.7.2 Indication of the method of notification (i.e. mail, phone, e-mail)

6.1.7.3 Report on what you have instructed customers to do with the recalled products

6.1.7.4 Name and title of the recall contact for each of its consignees

6.1.7.5 An explanation of the procedure to be followed in case the recalled product is to be returned

6.1.7.6 A proposed method of destruction (if applicable)

6.1.8 Public Notification

6.1.8.1 In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, after consultation with FDA, the company may issue a press release.

6.1.8.2 All customers to whom products are sold directly will be contacted by telephone, fax with mailed follow up, requesting them to stop all sales of the suspected batch, to take the necessary steps to return all stock of the recalled batch, and to recover distributed supplies from their clients (see Attachment 1 Sample Recall Letter).

6.1.8.3 The customers involved in further distribution of the recalled product will be instructed to contact any sub-customers that may have received the product and promptly initiate recall communication with them.

6.1.8.4 Letters to direct customers should include a return response form to enable the consignee to report the amount of the product available and its disposition (see Attachment 2 Sample Prepaid Return Response Form).

6.1.9 Evaluation of the Recall

6.1.9.1 The Recall Team will carry out effectiveness check for the recall to ensure that the notification letters were received, read, understood and instructions followed by the customer. This activity should be documented by the V.P. of Quality and Regulatory or designee.

6.1.9.2 If the effectiveness check indicates that the recall notification was not received, read and/or instructions followed, necessary steps should be taken to make the recall effective. These steps should involve sending out a follow up notification that better identifies the product, better explains the problem and/or provides better instructions to customers.

6.1.9.3 Recall status reports should be sent to the local FDA Recall Coordinator after initiating a recall on a monthly basis with following information: dates customers notified, number of customers notified, number of customers responding, quantity of recalled product returned or accounted for, details of your recall effectiveness checks.

6.1.9.4 The Recall Team will establish the root cause of the problem and such information will be provided to the local FDA Recall Coordinator. The Recall Team will propose the corrective and preventive action plan to prevent future occurrences of similar problems.

6.1.10 Disposition of Recalled Products

6.1.10.1 All products should be returned to the company following SOP E-501 Procedure for Returned Products.

6.1.10.2 All recalled product must be clearly identified, logged on Form E-501-F2 Returned Product Authorization Log, and placed in quarantine area.

6.1.10.3 Final disposition must be documented by V.P. of Quality and Regulatory Affairs or designee using forms E-501-F1 Returned Product Authorization and E-501-F2 Returned Product Authorization Log.

6.1.11 Termination of the recall – following receipt of all customer responses and after making sure the recall product has been recovered, corrected, reconditioned or destroyed; a final status report and documentation of recalled product disposition should be provided to the local FDA Recall Coordinator. The FDA will consider formal termination of the recall action and then notify the company.

6.1.12 Effectiveness Checks - After a recall is completed, FDA may follow-up to ensure that the product is destroyed and investigates why the product was deemed defective.

6.1.13 Recall Insurance Status – As an additional resource, recall insurance is available. If necessary, this service should be utilized. This will be at the discretion of the V. P. of Quality and Regulatory. A follow up with the Finance department is necessary to determine the current status and provider of the recall insurance.

7.0 Mock Recalls

7.1 Two random Mock Recalls are performed as a recall self-audit each year. This exercise may include a Traceability Exercise (which may include distribution of specific product lots, raw material ingredients and primary packaging). The objective/target reconciliation result is 100%, with an allowance of +/-2%. Executive Management shall review results.

Should this reconciliation fall outside of the allowance, a full investigation will be initiated as per SOP C-201 Deviation and Investigation Procedure.

7.1.1 Develop and execute a realistic plan.

7.1.2 Goals and Policies should address the following items:

7.1.2.1 Mitigate damage to the reputation of your company and brand

7.1.2.2 Mitigate the cost of a recall

7.1.2.3 Meet government regulations

7.1.3 Copies of all supporting materials (shipping records, production records, etc.) shall be retained to demonstrate how reconciliation occurred.

7.1.4 The Mock Recall exercise is performed to ensure the ability to identify the distribution location/trace activities of all products (Finished Product and Raw Material) of interest in the event of a product/process/equipment incident.

7.1.5 Mock recalls must be completed within a four (4) hour period.

7.1.5.1 Timeline for performing a Mock Recall during an onsite audit is at the discretion of the Auditor and may differ from the 4 hour requirement.

7.1.6 Mock Recalls are notated on the Internal Audit Schedule by Quarter, but may be unscheduled when performed.

7.1.7 Mock Recalls conducted by a 3rd party audit may also serve as a qualified random mock recall exercise requirement as outlined in the commitment of performing two random mock recalls per year.

7.2 The Recall Notification form (QS-107-F1) is used to note all pertinent information. A staff member is designated to manage the recall procedure and after completion, the data gathered from the Mock Recall is maintained by the Quality Assurance Department. The

time to complete the exercise is recorded on the form. All documentation associated with the Mock Recall should be notated as such (i.e. watermark, stamp or written "Mock Recall").

7.3 Executive Management Review

7.3.1 Recall activity is reviewed during Management Review Meetings.

8.0 Record Retention

8.1 Records for recall will be maintained in accordance with SOP C-502 Record Storage, Retention, and Destruction.

8.2 Recall documentation associated with a formal recall is retained by the QA Department.

9.0 Revision History

Revision	Date	Description of Changes	CCN	By
0	03/17/14	Replaces J-102. Added mock recall requirements.	14-0227	S. Millar
1	05/20/14	Updated SOP.	14-0437	S. Millar
2	09/09/14	Added Recall Team responsibilities.	14-0706	S. Millar
3	02/09/15	Added OTC reference. Added new contact information. Added new evaluation and recall flow. Added mock recall and internal audit schedule.	15-0137	S. Millar
4	03/01/16	Revised to reflect current recall team. Added reference to NSF/SQF. Updated FDA contact information. Added reference to legal counsel.	16-0193	S. Millar
5	06/05/17	Updated contact information.	17-0436	K. Burris
6	04/27/18	Updated contact information. Added Ref. to Canada MedEffect.	18-0147	S. Millar
7	09/08/18	Revised to reflect current Recall Team. QA retains Mock Recall Documentation. Document Control Department retains formal Recall documentation. Added ref. to Cosmetics to procedure. QS-107-F1 added ref to Cosmetic	18-0301	S. Millar
8	03/05/19	Revised to reflect current Recall Team. Corrected typographical errors.	19-0173	L. Vick
9	03/10/20	Added 7.17, instructions that a mock rock conducted by a 34d party audit may service as a qualified mock recall exercise requirement. Various organization title revisions and revised FDA contact information	CC-20-0178	L. Vick
10	06/24/21	Added section 7.1.5.1 for clarification of timeline during on site audits. Updated FDA contact info. Updated recall team members and contact info. Updated additional resources. Added statement regarding recall insurance. Changed recall completion time to 6 hours.	CC-21-0243	C. Mitchell
11	08/04/22	Revised to include applicable CFR reference and reflect current practices. Removed reference to Cosmetic Regulation.	CC-22-0339	S. Millar
12	03/22/23	Added statement to report to the RFR within 24 hours. Removed "District" from the title FDA Recall Coordinator. Updated recall team members and contact info.	CC-23-0154	C. Horelle
13	08/15/23	Add 3.4 in reference to NSF Gluten Free notification. Updated titles.	CC-23-0412	C. Horelle
14	12/13/23	Changed mock recall time to 4-hours and added allowance of reconciliation. Revised recall team members.	CC-23-0605	K. Burris

10.0 Attachments

10.1 Attachment 1 - Sample Recall Letter

10.2 Attachment 2 - Sample prepaid return response form

10.3 Attachment 3 - Complaint/Condition Evaluation Flow Chart

10.4 Attachment 4 - Recall Flow Chart

10.5 Attachment 5 - Example of a Traceability Activity Flow

10.6 Attachment 6 - FDA and Recall Team Contact Information

10.7 Attachment 7 - FDA Model Press Release Links/address and Additional Resources

Attachment 1 – Sample Recall Letter

(COMPANY LETTERHEAD)

URGENT :< PRODUCT NAME> RECALL

<Contact Name or Department>
<Firm Name>
<Address>
<City /state/zip>

Dear Sir/Madam,

This is to inform you of a product recall involving:

PRODUCT NAME:
PRODUCT DESCRIPTION:
BATCH NUMBER:
UPC CODES:
See enclosed product label <helpful for retailers/users in identifying the recalled product>

This recall has been initiated due to the following reason<Insert reason for recall>
Use of this product may cause <Insert any potential health hazard>.

Our records indicate that you purchased or were supplied with the following quantities of the subject product, on the date(s) below:

Date: Quantity:

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please immediately identify and contact your customers, notify them at once of this product recall and have them return their outstanding recalled stocks. Notify your customers by including a copy of this recall notification letter.

NO FURTHER SALES OR CONSUMPTION OF THIS PRODUCT ARE TO BE MADE. Please return all stocks immediately, at our expense; upon receipt the merchandise will be replaced without charge or you will be issued with a credit note to cover the cost of merchandise and return shipping expense.
The merchandise should be returned to:

<Insert company name, complete address, and phone number>

Please complete and return the enclosed response form as soon as possible.
If you have any question, call <telephone number>

This recall is being made with the knowledge of the Food and Drug Administration. This recall has classified as _____ (if classified).

Your assistance is appreciated and necessary to prevent <i.e. consumer illness or patient harm>. Thank you for your immediate attention to this matter.

Sincerely,
CEO [or delegate]

Attachment 2 – Sample Prepaid Return Response Form

(COMPANY LETTERHEAD)

PRODUCT:
BATCH NO(S):

Please check all appropriate boxes:
□ I have read and understand the recall instructions provided in the <date> letter.
□ I have checked my stocks and have quarantined inventory consisting of
_____ <units or cases>
□ I have identified and notified my customers that were shipped or may have been shipped this product.
Attached is a list of customers who received or may have received this product.
Please notify my customers.

We acknowledge that no further sales of this product are to be made. Any balance of stock will be returned without delay to < insert company name, complete address and telephone number>

Any adverse events associated with recalled product? □Yes □No
If yes, please explain: _____

Please check the appropriate box (es) to describe your business

□ Wholesaler/distributor □ Repacker
□ Manufacturer □ Hospital/medical facility
□ Retailer □ Pharmacy - retail

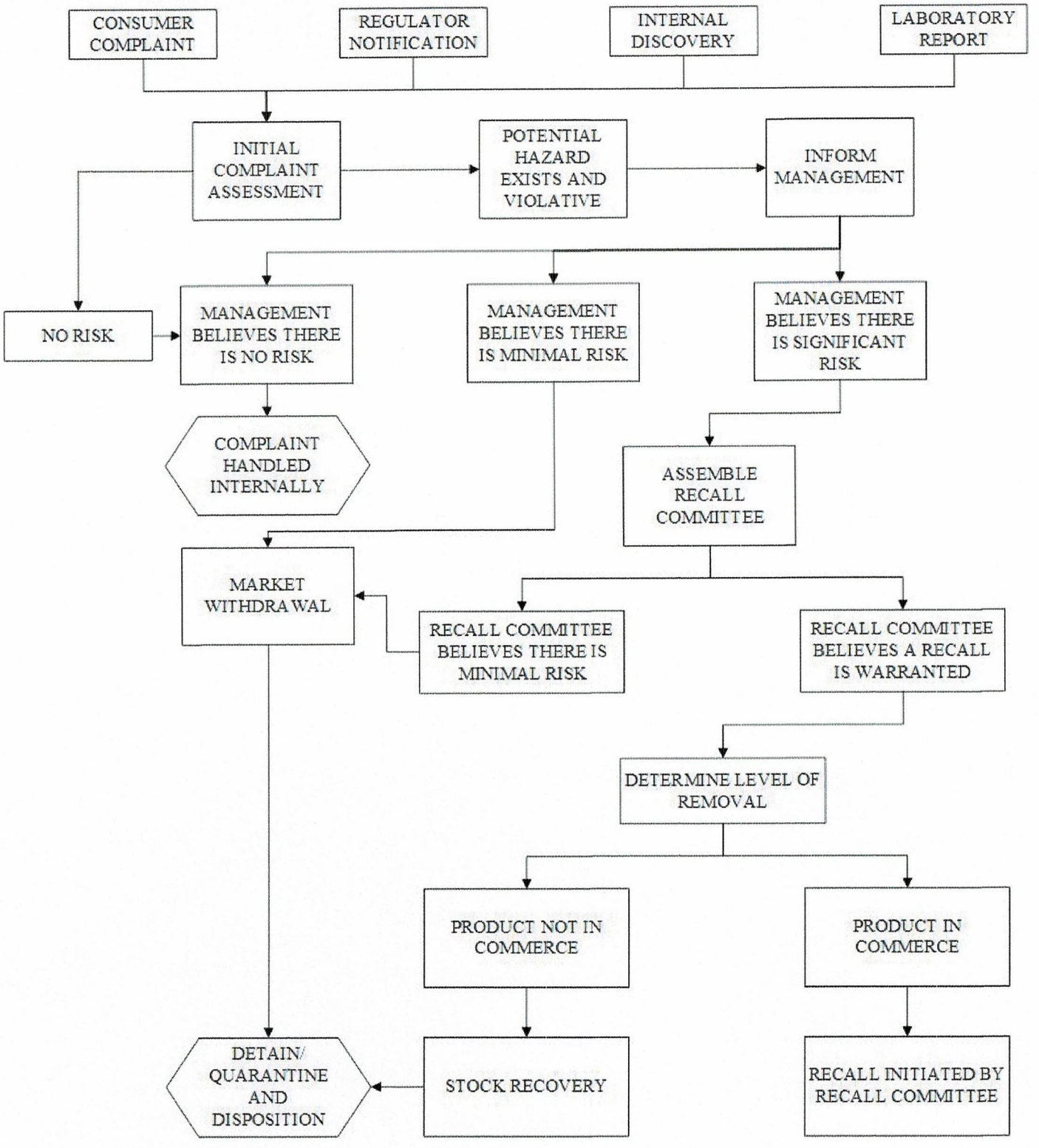
□ Other: _____

Name: _____
Title: _____
Phone number: _____

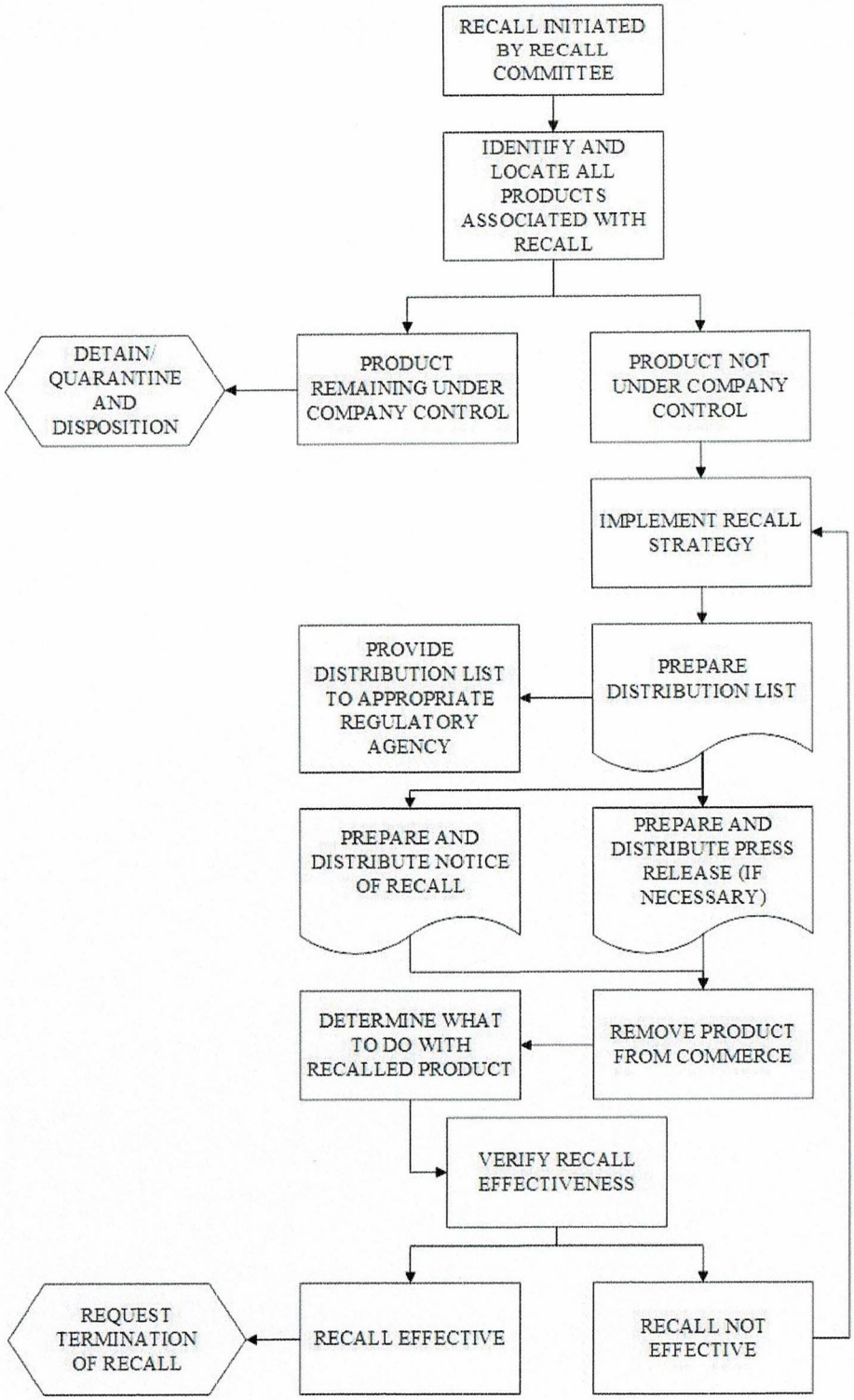
Firm name: _____
Address: _____
City/state: _____

Please fax the completed response form to Fax # < >, Attn. < >
Or mail to:
<Insert company name, complete address and phone number>

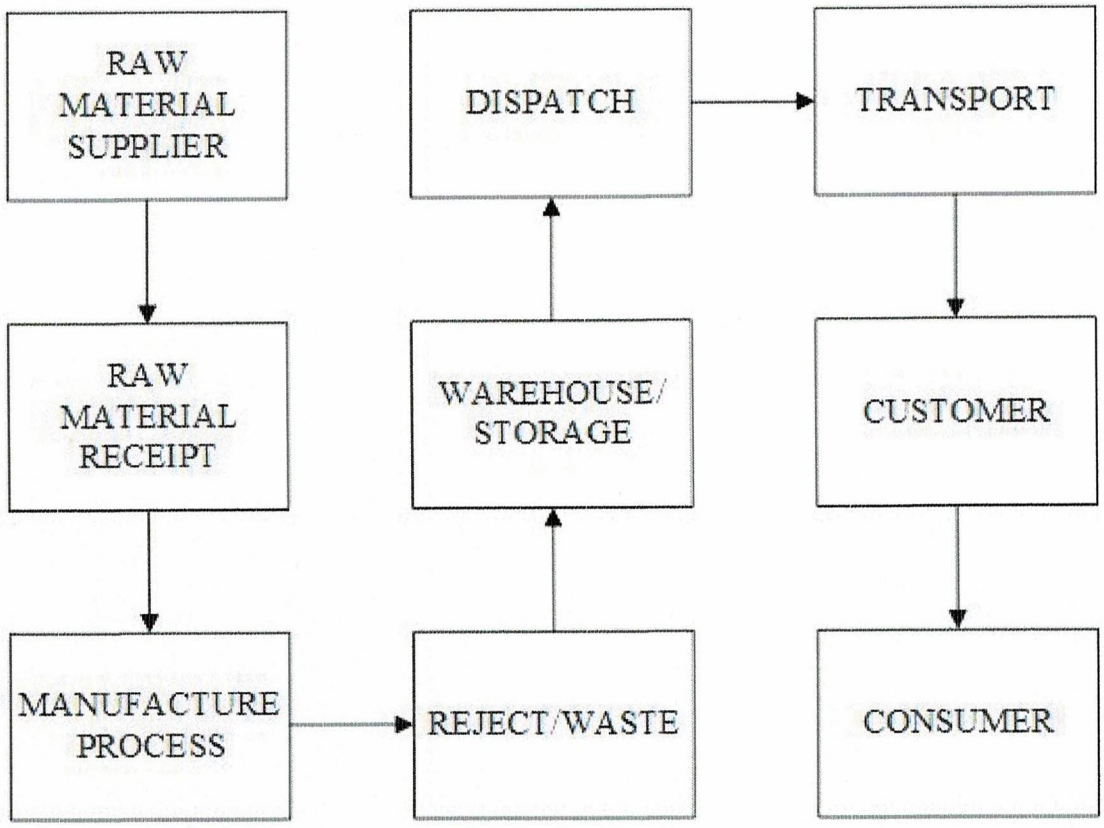
Attachment 3 – Complaint/Condition Evaluation Flow Chart



Attachment 4 – Recall Flow Chart



Attachment 5 – Example of a Traceability Activity Flow



Attachment 6 – Contact Information

ORA District and Headquarters Recall Coordinators

FDA Contact Information
FDA Southeast Region Recall Contact Information
Office of Regulatory Affairs
Florida District:
FL
Human and Animal Food & Cosmetics

Wanda J. Torres
Division of Human and Animal Food Operations East IV
466 Fernandez Juncos Avenue
San Juan, PR 00901-3223
Phone: 787-729-8709
Fax: 787-729-8826
E-mail: Orahafeast4recalls@fda.hhs.gov

Florida District:
FL
Pharmaceutical

Kenitra Hewitt
Division of Pharmaceutical Quality Operations II
501 West Felix Street Suite 1103
Fort Worth, TX 76115
Phone: 817-334-5218
E-mail: orapharm2recalls@fda.hhs.gov

Headquarters

Cecilia M. Wolyniak
ORA
Office of Strategic Planning and Operational Policy
Recall Branch
WO 32 RM 4352
10903 New Hampshire Ave.
Silver Spring, MD 20993
Phone: 301-796-8209E-mail: orarecalloe@fda.hhs.gov

Attachment 6 – Contact Information (Cont'd)

Recall Team Contact Information

The receptionist will retain all contact information, should the team need to be assembled.

CEO
Ivan Ilchev
8031 114th Avenue, Suite 4000
Largo, FL 33773
727-220-1365

VP of Quality and Regulatory Affairs
Dennis Herd
8031 114th Avenue, Suite 4000
Largo, FL 33773
727-220-1281

CFO
Michael Cawley
8031 114th Avenue, Suite 4000
Largo, FL 337733
727-220-1282

Quality Assurance Director
Kimberlee Burris
8031 114th Avenue Suite 4000
Largo, FL 33773
727-220-1290

Quality Control Director
Jennifer Sassman
8031 114th Avenue Suite 4000
Largo, FL 33773
727-220-1333

Director of Supply Chain
Millie Zhou
8031 114th Avenue Suite 4000
Largo, FL 33773
727-220-1365

Chief Operating Officer
Matthew Keib
8031 114th Avenue Suite 4000
Largo, FL 33773
727-273-1759

Attachment 7 – FDA Model Press Release Links and Additional Resources

Model Press Releases

Allergens (Allergy Alert)
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm

Listeria monocytogenes
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm

E. coli 0157:H7
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129287.htm

Human Drug Model Press Release
http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm272194.htm

FDA Guidance for Written Recall Notification Letters
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls

Additional Resources

Termination of Recall – 21 CFR Sec. 7.55
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=7.55

Industry Guidance: Information on Recalls of FDA Regulated Products

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls
US Food and Drug Administration
http://www.fda.gov/

Recall Policy – 21 CFR Recall Regulations Sect. 7.40
http://www.gpo.gov/fdsys/pkg/CFR-2004-title21-vol1/xml/CFR-2004-title21-vol1-sec7-40.xml

USDA (FSIS –Food Safety and Inspection Service)
http://www.fsis.usda.gov/wps/portal/fsis/home

Center for Disease Control
http://www.cdc.gov/

Guidance for Industry: Product Recalls, including Removals and Corrections
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-correction

Reportable Food Registry for Industry
https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry

ION Nutritional Labs	Recall Notification Form		
	Form: QS-107-F1	CCR No. CC-23-0605	Revision: 6

Item Information			
Product Type:	☐ Dietary Supplement ☐ OTC ☐ Pet ☐ Cosmetic ☐ Other (specify): _____		
Product Name:			
Product Description:			
Indication:			
Expiry Date:			
Batch Number:		**UPC Code:**	
Packaging Information:			
Manufacturer Information			
Name:			
Address:			
Contact Person:			
Title:			
Phone Number:			
Email Address:			
Fax Number:			
Recalling Firm Information			
Name:			
Address:			
Contact Person:			
Title:			
Phone Number:			
Email Address:			
Fax Number:			
Most Responsible Individual for Recalling Firm / Public Contact			
Name:			
Title:			
Address:			
Phone Number:			
Email Address:			
Fax Number:			