Application for Food Establishment Permit

Alaska Department of Environmental Conservation
Division of Environmental Health
Food Safety and Sanitation Program

Permit ID: _____

Section 1- GENERAL INFORMATION *(All applicants complete entire section – please print).*

Purpose (check one) ☒ New ☐ Information Change ☐ Extensive Remodel ☐ Change of owner/operator ☐ Reactivate

Owner/Business Information	Name of Entity or Owner Responsible for Food Service High Bush Buds, Inc.		AK Business License # 1036025	
	Business/Corporate Mailing Address 1009 CROW CT.	City KENAI	State AK	Zip 99611
	Business/Corporate Phone 907-398-0202	Email info@luckyraven.com		
	Owner(s) or Corporate Officer(s) & Title(s) or Responsible Party Patricia Patterson -President		Fax	
	Type of Entity ☐ **Individual** ☐ **Partnership** ☒ **Corporation** ☐ **Other:**			
Establishment Information	Establishment Name High Bush Buds	Physical Location 60.302000, -151.050000	Nearest Community Soldotna	
	Establishment Mailing Address 1009 CROW CT	City KENAI	State AK	Zip 99611
	Establishment Phone	Fax	Contact Person	
	Establishment Physical Address 36312 Irons Ave., Suite 2	City Soldotna	State AK	Zip 99669

SEATING: (Food Service Only) ☒ **N/A** ☐ **25 or less** ☐ **26-100** ☐ **> 101**

TYPE OF OPERATION *Please describe the type of facility you plan to open below (i.e. restaurant, bar, grocery store, etc.)*

Marijuana Retail Store - every edible product will be prepackage and no consumption will be on-site - more akin to a convenience store.

SECTION 2 – NEW OR EXTENSIVELY REMODELED FACILITIES

a. A plan review will be required if your facility has never been permitted by the Alaska's Food Safety and Sanitation Program; has not had an active permit in the last five years; will be extensively remodeled; or is a new construction. If any of these apply, a Plan Review Application is required to process your application. Have you attached the Plan Review Application? ☒ **Yes** ☐ **No**

SECTION 3 – COMPLETE FOR ALL FOOD ESTABLISHMENTS *(Check all that apply)*

FOOD SERVICE ESTABLISHMENTS

a. A copy of your menu will be required. Have you attached a copy of the proposed menu? N/A ☐ **Yes** ☐ **No**

b. Attach appropriate label, placard, or menu notation for the consumer advisories if you serve:
☐ Wild Mushrooms ☐ Unpasteurized juices ☐ Farmed halibut, salmon, or sablefish
☐ Raw/undercooked animal foods such as beef, shell eggs, lamb, pork, poultry, seafood, and shellfish.

c. Methods of food preparation (check the one that most closely describes the establishment:
☐ Assembly of Ready to Eat Foods ☐ Cook and Serve
☐ Hot or cold Service for 2 hours or more is done
☐ Complex (Preparation 1 day or more in advance, cooling and reheating is done).
**Establishment will not prepare food it will purchase prepackaged products for sale to consumers

d. Style of Service: ☐ Counter Service ☐ Self Service (i.e. buffet line, salad bar) ☐ Table Service
☒ Other: **Prepackaged edibles for off site consumption only

e. Do you plan to operate as a caterer? ☐ **Yes** ☒ **No**
If *yes,* list all the equipment used to protect food from contamination and maintain product temperature during:
Transportation: Hot or Cold Holding:

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Permit ID(s)_____ Establishment Name(s)_____

f.	Will your food establishment be a kiosk or mobile unit?	☐ Yes	☒ No
	Are employee toilets available within 200 feet? *If you have an agreement with another business to use their restrooms, please attach written verification.*	☐ Yes	☐ No
	Portable water tanks, plumbing, and hoses are NSF or FDA approved components?	☐ Yes	☐ No
	If you have a kiosk, is it located outside of a building?	☐ Yes	☐ No
	Will you have a service provide water or remove wastewater? *If yes, provide a letter of agreement from water hauler or wastewater hauler outlining services provided and frequency.*	☐ Yes	☐ No
g.	Will another permitted food establishment (commissary) provide support to your facility? If yes, attach a copy of the Commissary Agreement.	☐ Yes	☒ No

FOOD PROCESSORS

a. A copy of a label for each type of product you will produce is required. Have you attached food labels of each product to be produced? ☐ Yes ☒ No

b. Describe who you will be distributing your product to (i.e. grocery stores, etc):
Prepackaged marijuana edible products will be distributed from High Bush Buds

c. Will you be doing any of the following processes? Check all that apply.

☐ Reduced Oxygen Packaging ☐ Smoking ☐ Other:
☐ Low Acid Canned Foods ☐ Curing
☐ Shelf Stable Acidified Foods ☐ Dehydrating

Be sure to check with your local Environmental Health Officer for any applicable forms and FDA requirements.

d. Do you have a HACCP Plan? ☐ Yes ☒ No ☒ N/A
Required for high hazard food processors such as smoking, curing, acidifying, dehydrating, thermally processing low acid foods, reduced oxygen packaging, etc.

e. You are required to have a product coding system and a recall plan. Have you attached a copy of the coding system and recall procedures? ☒ Yes ☐ No

MOBILE RETAIL VENDOR SELLING SEAFOOD

a. A list of products that you will be selling is required. Have you attached a copy of the list of products? ☐ Yes ☒ No

b. Provide names of suppliers where you will be purchasing your product:
Unknown - no manufacturing companies are approved by the Alaska Marijuana Control Board to date.

c. Will ***all*** of your product be prepackaged? ☒ Yes ☐ No

d. Will another permitted food establishment (commissary) provide support to your facility? If yes, attach a copy of the Commissary Agreement. ☐ Yes ☒ No

MACHINES VENDING POTENTIALLY HAZARDOUS FOODS

a. Have you attached the label that will be affixed to the front of each machine with name, physical address, and phone number of the permitted food establishment servicing the machine? ☐ Yes ☒ No

SECTION 4 – Food Managers Certification/Alaska Safe Food Worker Card

a. Have you attached a copy of a Food Manager's Certification? ☐ Yes ☐ No ☒ N/A
The operator of a food establishment that serves and prepares unwrapped or unpackaged food, except for a bar, tavern, or limited food service, must have at least one Certified Food Protection Manager who is involved in the daily operations of the establishment.

b. Does everyone who works or will work at the food establishment have a Food Worker Card? ☒ Yes ☐ No ☐ N/A
An operator of a food establishment shall keep on file a copy of the Food Worker Card issued by the department for each employed food worker and make the copy available to the Department upon request.

I declare, under penalty of unsworn falsification, that this application (including any accompanying statements) has been examined by me and to the best of my knowledge and belief is true, correct, and complete. I agree to pay all fees before operating.

Applicant's Signature Patricia Patterson **Date** 8/29/16

Applicant's Printed Name PATRICIA PATTERSON **Title** PRESIDENT

Plan Review Application

Alaska Department of Environmental Conservation
Division of Environmental Health
Food Safety and Sanitation Program

Permit ID: _____

Section A- General Information *(All applicants complete entire section – please print).*

Purpose (check one) ☐ **New Construction** ☒ **Remodel of Existing Structure** ☐ **Reactivation**

General Information		
Establishment Name: High Bush Buds, Inc.		Date
Plan Review Contact Name: Patricia Patterson		
Phone Number: 907-398-0202	Email: info@luckyraven.com	
Address: 36312 Irons Ave., Suite 2, Soldotna, AK 99669		
Operating Days/Hours: M-Sunday 9AM -8pm	Proposed Opening Date: TBD	

If you are proposing to build a new food establishment or extensive remodeling of an existing food establishment in Alaska (except in the Municipality of Anchorage), you must submit a **completed Plan Review Packet 30 days prior to construction**. Additional information regarding calculations and drawings can be found in the Plan Review Guide.

Please Note: Failure to provide all the required information may delay the plan review process and permit issuance.

REQUIRED DOCUMENTATION LIST (*Include the following in your packet*)

- ☒ Food Establishment Application
- ☐ Fees
- ☒ Plot Plan
- ☒ Floor Plan
- ☐ Plumbing Schematic
- ☐ Complete list of equipment (including manufacturer's specifications)

SECTION B – REQUIRED DOCUMENTATION

a. **Potable Water Supply.** Have plans been submitted to the Drinking Water Program as required by 18 AAC 80?

☐ **Yes*** ☒ **No** ☐ **N/A** (Municipal Water Supply) ***Specify in comments.***

Comments:

Attach a confirmation email or letter from the Drinking Water Program stating that the system has been approved.

b. **Wastewater Disposal System.** Have plans been submitted to the Wastewater Program as specified by 18 AAC 72?

☐ **Yes*** ☒ **No** ☐ **N/A** (Municipal System) ***Specify in comments.***

Comments: AMCO should submit the waste plan to the appropriate entities during review process.

Attach a confirmation email or letter from the Wastewater Program stating that the system has been approved.

c. **Solid Waste Disposal.** Please describe how you plan to dispose of your solid waste:

There will be no solid waste

d. **Plot Plan.** Have you included a detailed to scale drawing of the plot plan including: ☒ **Yes** ☐ **No**

- ☒ All buildings
- ☐ Refuse storage site
- ☐ Potable water supply
- ☐ Outside walk-in cooler(s)/freezer(s)
- ☐ Outside storage areas
- ☐ Oil/Fuel tanks
- ☐ Access for deliveries
- ☐ Sewage disposal system
- ☒ Identify nearby roads, streets, other landmarks, and/or give GPS coordinates

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Permit ID(s)_____ Establishment Name(s)_____

e. **Floor Plan.** A floor plan with the listed components must be submitted as part of the application packet. Have you included a floor plan? ☒ **Yes** ☐ **No**

☒ Layout and purpose of each room
☐ Type and location of lighting
☒ Location of fixed equipment and plumbing features
☐ Type and location of ventilation, both building and local systems
☐ Size, construction, and design of fixed equipment
☒ Location of restrooms, including the number of toilets and handwash sinks.

f. **Plumbing Schematic.** A plumbing schematic with the listed components must be submitted as part of the application packet. Have you included a detailed drawing of the plumbing schematic? ☐ **Yes** ☒ **No**

☐ Plumbing schematic showing each hot, cold, and wastewater line.
☐ Plumbing connection to the wastewater line (direct vs. indirect)
☐ Hot water capacity

Have you contacted the State Plumbing Inspector? ☐ **Yes** ☒ **No**

G **Fire Marshall.** Have you contacted the State Fire Marshall? ☒ **Yes** ☐ **No**

Please describe your ventilation/hood system:

Fire Marshall will be contacted by AMCO to review the retail marijuana application.

SECTION C – ADDITIONAL INFORMATION

a. **Storage**. How often will you receive food deliveries? Do you have adequate storage to support your operation? Consult the Plan Review Guide for information about storage capacity.

TBD

b. **Dressing Rooms and Locker Rooms.** Describe how employee clothing, belongings, etc will be stored:

Cabinet to store their belongings.

c. **Poisonous/Toxic Materials**. Describe location and means to store poisonous or toxic materials:

None

d. **Floors/Walls/Ceilings**. Describe how the floors, walls, ceilings, and shelving will be finished (tile, paint, etc):

Floors - Heated concrete floors. Ceilings in retail space- Tongue and groove 100% Pine wood. Ceilings in safe room and sink room - standard drywall, textured and painted. Walls - standard drywall, textured and painted. Shelving - either wood or "wood composite" product purchased at Home Depot.

e. **Warewashing:** Describe how dishes, utensil, and equipment will be washed:

No dishes or utensils will be used

f. **Linens.** Describe how soiled and clean clothing/linens will be stored and where they will be cleaned:

N/A

SECTION D

I declare, under penalty of unsworn falsification, that this application (including any accompanying statements) has been examined by me and to the best of my knowledge and belief is true, correct, and complete. I agree to pay all fees before operating.

Applicant's Signature Pat Patterson **Date** 9/1/16

Applicant's Printed Name Patricia Patterson **Title** President

Recall Plan Table of Contents

Version Verification 2
Introduction 3
Statement of Recall Plan 3
Recall Plan Flow Chart 4
Complaint Evaluation Flow Chart 5
Recall Flow Chart 6
Recall Procedures 6
- Assignment of Roles and Responsibilities 6
  - Recall Coordinator
  - Recall Committee
  - Responsibilities
- Evaluation of the Complaint or Condition 7
- Identification of Implicated Products 7
- Notification of Affected Parties 8
- Removal of Affected Products 8
  - Removal
  - Control of Affected Product
  - Product Disposition
  - Recall Effectiveness
  - Recall Termination

Mock Recall 9
Appendix A – Contact Information 10
Appendix B – Templates 11
Appendix C – Additional Information 12
Appendix D – Assigned Responsibilities 13

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High Bush Buds' Plan
Version Verification

High Bush Buds' Plan shall be reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other factors change. The Plan will also be reviewed after any company recall.

Version _(_____)_

Approved by _____
Name of Approver

Title

Date Approved _____

Introduction

The primary goal of a food recall is to protect public health by removing products from commerce that have been determined to be unsafe. A recall plan can aid in the execution of a recall by apportioning duties, centralizing current contact information, and providing prewritten templates for communications. Key Individuals that will be participating in a company recall should review the recall plan and be familiar with the execution of the plan.

Coding – Metrc is the program the State of Alaska has adopted to implement and track all marijuana products and marijuana. Each product will have a batch code number and will be traceable to the manufacturer and to the cultivator. Metrc is the coding system that this establishment will utilize to track and identify any product needing to be recalled.

Statement of Recall Plan

High Bush Buds maintains a recall plan which provides specific procedures, defines terms, and assigns roles and responsibilities when a food safety issue arises with any of our products.

The plan will be activated whenever a potential recall requirement arises and includes the following elements:

1. Recall committee member designations
2. Recall responsibility assignments
3. Key personnel and external contact information
4. Recall procedures
5. Communication templates

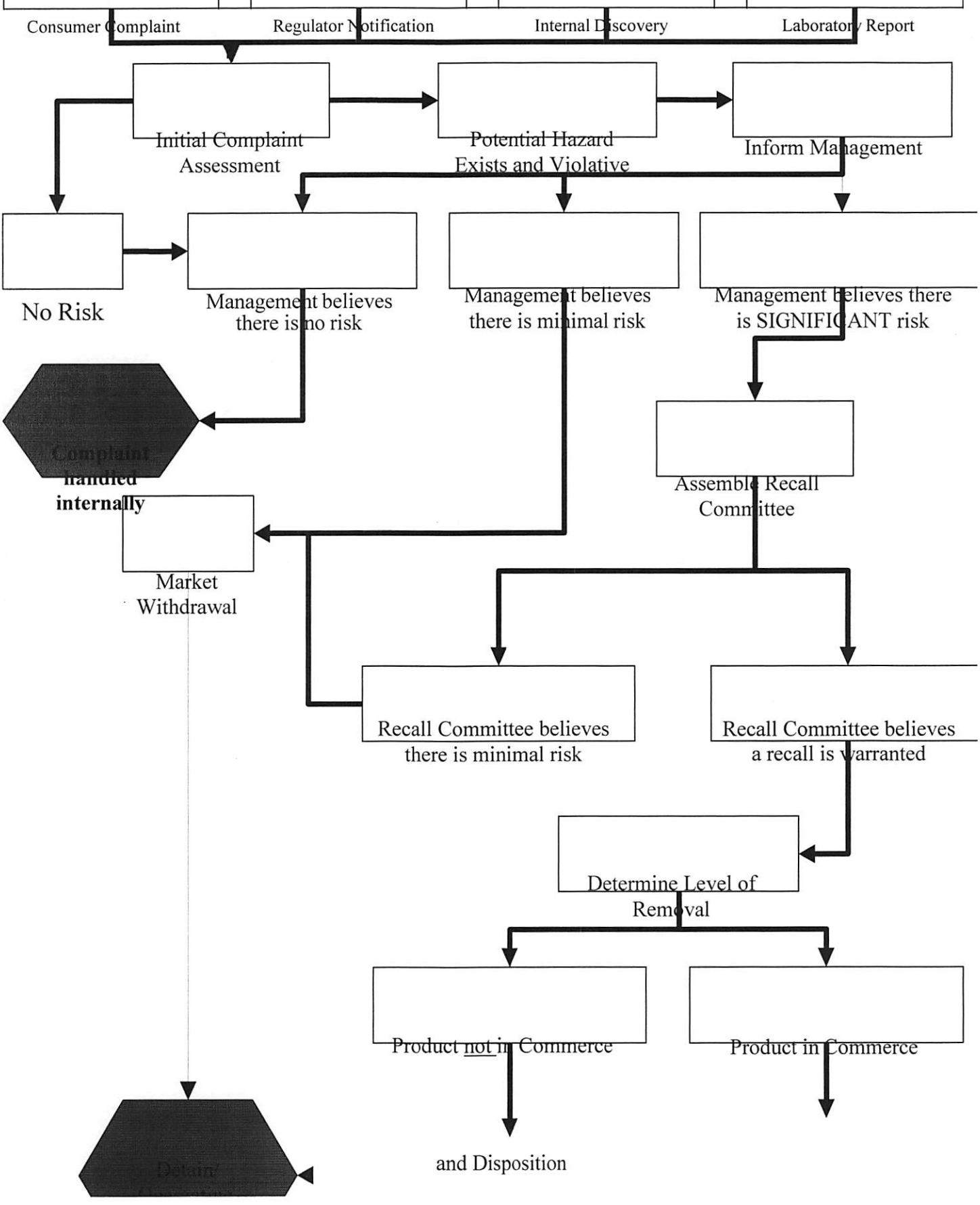
Success of the plan relies on the proper execution of plan elements and up-to-date information.

Recall Plan Flow Charts

The following two diagrams are graphical representations of the various steps of a recall. Figure 1, illustrates the typical evaluation of complaints or conditions which may lead to a recall. Figure 2, outlines the various steps of a recall.

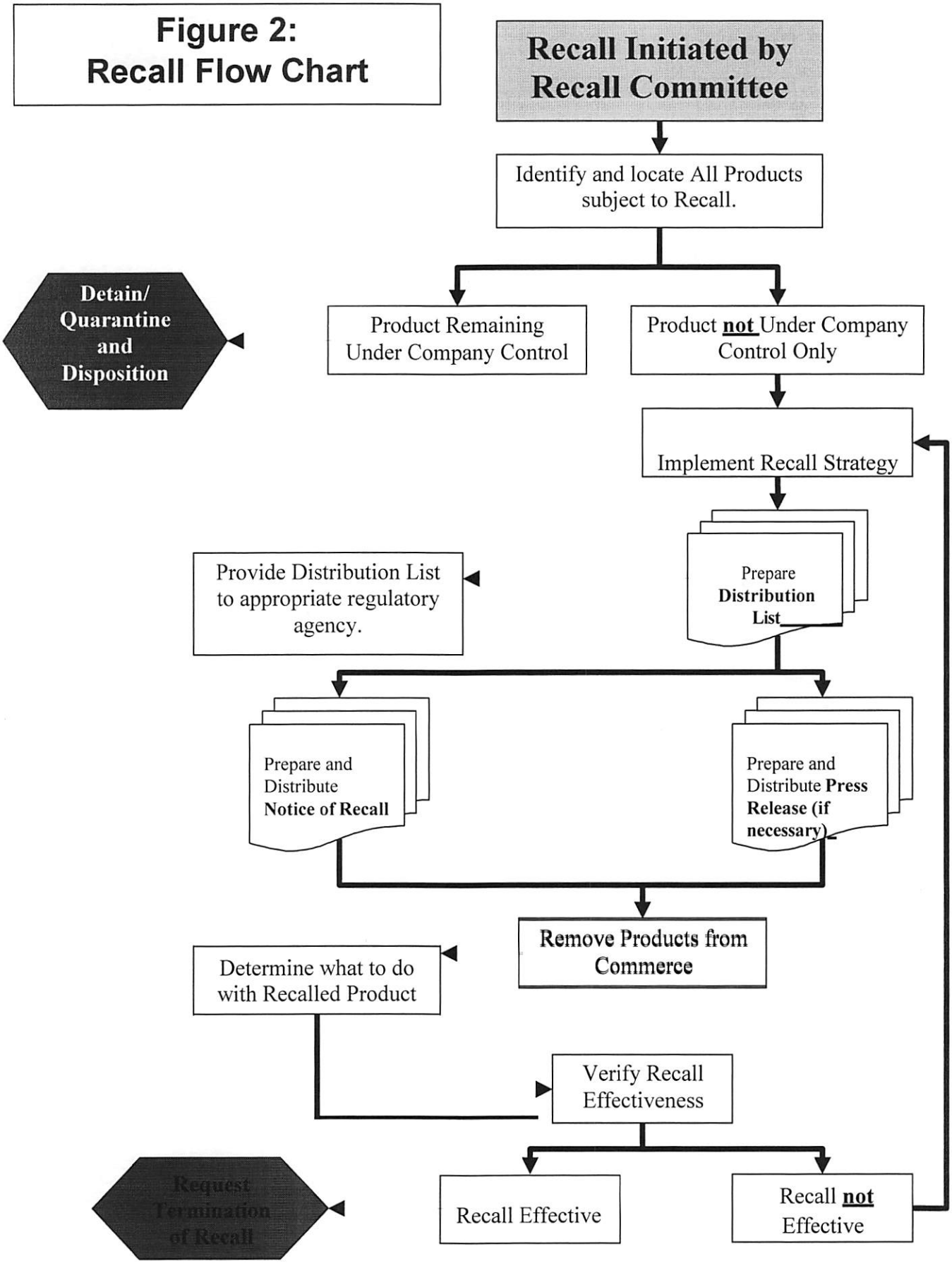
Figure 1: Complaint/Condition Evaluation Flow Chart

Figure 1: Complaint/Condition Evaluation Flow Chart



Recall Initiated by Recall Committee

Figure 2: Recall Flow Chart



Recall Procedures

The recall procedure outlines the activities that High Bush Buds will take to manage the recall of our product(s) which has/have been determined to be unsafe and/or subject to regulatory action. The procedure contains the major recall elements below:

- **Assignment of Roles and Responsibilities**
- **Evaluation of the Complaint or Condition**
- **Identification of Implicated Products**
- **Notification of Affected Parties**
- **Removal of Affected Products**

Assignment of Roles and Responsibilities

The roles and responsibilities of every individual on the Recall Committee should be clearly defined in the recall plan. Oversight of the following recall elements should be assigned to a member of the Recall team. Note that individuals may be responsible for more than one recall element.

Recall Coordinator

The recall co-coordinator, has been given authority by the management of High Bush Buds to execute the activities of the recall. Responsibilities of the Recall Coordinator include, but are not limited to:

- Assure the documentation of all recall decisions and actions in a master recall file.
- Initiate the formation of the recall committee.
- Activate various components within the company for priority assistance.
- Make recall decisions on behalf of our Company.
- Manage and coordinate the implementation of the company's product recall.
- Keep management informed at all stages of the recall.

Recall Committee

High Bush BudsProduct Recall Committee is composed of the various components of the company's organization. The following functions should be represented on the committee (an individual may be responsible for more than one function):

- Management (Administration)
- Recall Coordinator
- Accounting
- Consumer Affairs/Public Relations
- Customer Service
- Distribution and Supply
- Information Technology
- Legal Counsel
- Marketing
- Operations
- Production
- Purchasing
- Quality Assurance
- Sales
- Maintenance
- Records Management
- Regulatory Affairs
- Sanitation

Note: Outside resources may need to be obtained for some of the functions.

Responsibilities
Individual recall activities should be assigned prior to a recall event to avoid confusion during a recall. Assignment of the recall responsibilities are found in Appendix D (assign an individual to each activity).

Evaluation of the Complaint or Condition

Complaint receipt, processing, and evaluation are the first steps in the recall process. The steps involved in the evaluation process are:

- Receive the complaint – A file should be maintained containing any product complaints the company receives. Information that should be maintained in the product complaint file is:
    - i. Complainant contact information
    - ii. Reported problem with the product
    - iii. Product Identification
    - iv. Product Storage
    - v. Product purchase date and location
    - vi. Illness and Injury details
- Provide the complaint to knowledgeable staff for initial evaluation. If an initial assessment indicates a recall may be necessary, the Recall Coordinator assembles the Recall Committee for a full evaluation.
- Determine the hazard and evaluate the safety concerns with the product.
- Determine the product removal strategy appropriate to the threat and location in commerce.
- Contact the appropriate regulatory authorities.
- Alert legal counsel, insurance, etc. as appropriate.
- Maintain a log of the events of the recall including information such as dates, actions, communications, and decisions.

Identification of Implicated Products

It is High Bush Buds responsibility to ensure the identification of all products and quantities of products implicated in the recall. In addition, determination should be made if any other codes, brands or sizes of product handled by the company are affected.

A distribution list should be prepared as part of the Identification process. The distribution list should at minimum identify:

- Account name (consignees) that received the recalled product(s)
- Account addresses
- Contact names
- Contact telephone numbers
- Type of account (e.g., manufacturer, distributor, retailer)

Additional information relating to product information may include:

- Amount of product received/shipped
- Product ship date(s)
- Amount of product returned
- Amount of product consumed

A link to the FDA Distribution Template can be found in Appendix B.

Notification of Affected Parties

Notifications during a recall must be done in a timely manner and should include the appropriate regulatory agencies, the product distribution chain, and consumers when necessary. Recall notices are typically used to notify regulatory agencies and those businesses in the distribution chain. Press releases are generally oriented to consumers, but may be used to notify any affected party.

- Regulatory Agencies should be notified at the earliest opportunity after the decision has been made to conduct a recall. Regulatory guidance may be found at: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm.
    - Subsequent to the initial notification, the regulatory authority should be updated throughout the recall process.
- Distribution Chain contacts will be notified by appropriate means (telephone, fax, email, letter, etc.). It is recommended that a written recall notice be provided to all consignees. The Recall Notice **must** include all relevant recall information (see Appendix B, section (a)(ii)).
    - Confirm receipt of the Notice of Recall with all accounts. A record of all account communications should be maintained.
- Consumers should be notified by the most effective method available. If appropriate, a press release can be used to notify consumers. Considerations for preparing a press release include:
    - Issuance of a press release should be the highest priority and should be issued promptly.
    - The local FDA District Recall Coordinator should be consulted before issuance of a press release whenever possible.
    - All relevant information should be included in the press release (seesample templates in Appendix B).

Removal of Affected Product

The procedure for product removal can be divided into five components including: removal, control, and disposition of affected product, recall effectiveness, and recall termination.

Removal

All reasonable efforts must be made to remove affected products from commerce.

- Products in commerce should be detained, segregated, and handled in a manner determined by the recalling firm.
- Products that are still in the recalling firm's control (e.g. inventory located onsite, in transit, in off-site storage, and in offsite distribution) should be detained, and segregated.
- All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

Control of Recalled Product

When High Bush Buds chooses to retain recalled product, control must be regained to prevent reentry of the product into commerce.

- All affected product returned will be clearly marked, not for sale or distribution, and stored in an area that is separated from any other foodproducts.

All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

Product Disposition

The final disposition of the recovered product must be determined. The final disposition must be reviewed and approved by the regulatory agency. Options include:

- Redirection – Products may be redirected for uses other than human consumption.
- Destruction - Products determined to be unsafe for human consumption may be destroyed or denatured, and disposed by appropriate means.
- Recondition – Products may be reworked to remove the safety risk. For example, would be relabeling a product to declare an allergen originally omitted from the label.

All quantities, identification codes, and disposition shall be documented.

Recall Effectiveness

High Bush Buds is responsible for determining whether the recall is effective. Recall Effectiveness Checks verify that all consignees have been notified and have taken the appropriate action. Steps include:

- Verifying that all consignees have received the notification.
- Verifying that consignees have taken appropriate action.
- If the response from our consignees is less than 100%, then the recall should be deemed ineffective and the recall strategy should be reassessed. Certain circumstances (e.g. amount of product actually returned vs. expected, potential for consumption, shelf-life, etc.) may also require a reassessment of the recall strategy.

All verifications shall be documented.

Termination of a recall

Termination of the recall may be considered after all reasonable efforts have been made to remove the affected products from commerce, including reconciliation, recall effectiveness, and disposition.

A termination of the recall may be requested by submitting a written request to the regulatory authorities. Guidance for the termination of a recall is provided in Appendix C.

Mock Recall

In addition to an annual verification of the recall plan, High Bush Buds will conduct a mock recall annually or whenever there are significant changes to the plan or personnel. The mock recall will include the following elements:

- Selecting a product which has reached the consumer market.
- Tracing the product from the raw ingredient (e.g. source) level to the finished product in the marketplace.
- Verifying communications systems (e.g. contact information, test emails and faxes, etc.) to outside contacts.
- Modifying the recall plan to correct any problems encountered during the test.

Records of these mock recalls will be documented and filed appropriately.

Appendix A – Contact Information

Recall Committee and Key Personnel Contact Information

The contact information including phone number, fax number, email address, and alternate 24/7 information of all committee members, their alternates, and "outside" key personnel should be confirmed and updated as often as necessary to assure accuracy.

Contact Information

- Recall Committee (24/7)
    i. Recall Committee Members 907-398-0202

Appendix B – Templates

1. Communication Templates
    i. Model Press Releases(FDA)
        a. Allergens (Allergy Alert)
           http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm
        b. Listeria monocytogenes
           http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm
        c. Clostridium botulinum
           http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129273.htm
        d. Salmonella (all serotypes)
           http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129275.htm
        e. E. coli 0157:H7
           http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129287.htm
    ii. FDA Guidance for Written Recall Notification Letters
        http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm
    iii. FDB Distribution List Template
        http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/fdb%20eru%20Gde%20DistListTemp.xls
2. Recall Events Log (should include the following information):
    i. Name of the person creating the action
    ii. Dates
    iii. Actions
    iv. Communications
    v. Decisions
    vi. Product disposition
3. Recalled Product Information Data Sheet (should include the following information):
    i. Product description: brand, product name, size,etc.
    ii. Lot codes
    iii. Quantity of recalled product
    iv. Date of the action
    v. Action taken for each product

Appendix C – Additional Resources

1. Industry Guidance: Information on Recalls of FDA Regulated Products
   http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm

2. Recall policy – 21 CFR Recall Regulations Sec. 7.40
   http://edocket.access.gpo.gov/cfr_2004/aprqtr/21cfr7.40.htm

3. US Food and Drug Administration
   http://www.fda.gov/

4. USDA (FSIS)
   http://www.fsis.usda.gov/wps/portal/fsis/home

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

6. FDA District Recall Coordinators
   http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

7. FDA Guidance: Action levels for Poisonous or Deleterious Substances in Human and Animal Feed http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/chemicalcontaminantsmetalsnaturaltoxinspesticides/ucm077969.htm

8. FDA Defect Levels Handbook
   http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm056174.htm

APPENDIX D – Assigned Responsibilities

Sample Assignments (may include, but not limited to the following)

Assignment

1. Management of the Recall – (**Insert Name, Title**) is responsible for the coordination of all recall activities.
2. Assemble the Recall Committee – (**Insert Name, Title**) is responsible for communicating the decision to recall to the members of the Recall Committee and that each member knows their responsibilities.

Evaluation

1. Management Approval of the Recall – (**Insert Name, Title**) is responsible to decide if the recall should go forward.

Identification

1. Create a Product Recall Log – (**Insert Name, Title**) is responsible to create and maintain a product recall log to document all events, when they occur and the company's response to each.
2. Identify all Products to be Recalled – (**Insert Name, Title**) is responsible for identifying all products which need to be recalled.

Notification

1. Notify the Appropriate Regulatory Authority – (**Insert Name, Title**) is responsible for notifying the appropriate regulatory authority (use the contact information in the Recall Plan). Contacts shall only be made through the designated committee member. Recommended information to be submitted can be found in the FDA guidance document at: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm
2. Prepare the Press Release (if required) – (**Insert Name, Title**) is responsible for the recall press release if the decision to prepare a press release is made. Considerations for preparing a press release include:
    a. Issuance of a press release should be the highest priority and it should be issued promptly.
    b. Consult with your local District Recall Coordinator before issuance of a press release whenever possible.
    c. If the company decides to prepare the press release, include all relevant information (see sample templates in AppendixB)
3. Prepare the Distribution List – (**Insert Name, Title**) is responsible for preparing the recalled product distribution list. The FDB distribution list template requests account type, name, address, phone number, and contactname.
4. Prepare the Notice of Recall – (**Insert Name, Title**) is responsible for preparing the written notice includes all recall relevant information (see FDA Guidance for Written Recall Notification Letters inAppendix).
5. Distribute the Notice of Recall – (**Insert Name, Title**) is responsible for distribution of the Notice of Recall to all accounts that received the recalled product. Responsibilities include:
    d. Confirm receipt of the Notice of Recall with allaccounts.
    e. Contact accounts that have not responded to the request for conformation.
    f. Maintain records of the accountcommunications.

Removal

1. Detain and Segregate all Products to be Recalled which are in your Firm's Control – (**TBD**) – is responsible to ensure that all products to be recalled in the firm's control are not distributed (identify, detain, and segregate products on-site, in transit, off-site storage, and off–sitedistribution).
2. Control the recalled product(s) – (**TBD**) is responsible to ensure that recalled products do not re-enter commerce. Responsibilities include:
    a. Quarantine and clearly identify recalledproducts.
    b. Reconcile quantities, identification codes, and monitor recalled products.
    c. Document the returned products.
3. Decide what to do with the recalled product(s) – (**TBD**) is responsible for determining the action to be taken on the recalled product (destruction, reworking, and redirection). Other related responsibilities include:
    a. Determine if the regulatory authority requires actions such as witnessing destruction of the recalled product.
    b. Verify that the action taken has beeneffective.
    c. Document the action(s) taken.
4. Verify Recall Effectiveness – (**TBD**) – is responsible for verifying the effectiveness of the recall. Responsibilities include:
    a. Verify that distribution of recalled products hasceased.
    b. Verify that all consignees at the recall depth specified by the recall strategy have received notification about therecall.
    c. Verify that consignees have taken appropriateaction.
    d. Document all verifications.