1.0 Purpose

This procedure outlines the process for both *recall* and *withdrawal*. The main objectives of this plan are to:

- Stop the distribution and sale of the affected product.
- Effectively notify Management, customers, and regulatory authorities (i.e. FDA/HPFB).
- Efficiently remove the affected product from the market place.
- Remove the affected product from warehouses and/or distribution areas.
- Dispose of the affected product.
- Conduct a root cause analysis and report the effectiveness and outcome of actions taken.
- Implement a corrective action plan to prevent another recall/withdrawal.
- Conduct a debriefing meeting with Management upon completion of the event.

2.0 Scope

A *recall* is conducted to protect public health and safety. A *withdrawal* is generally undertaken for quality purposes or as a precautionary measure before an official recall. This procedure applies to both the Manufacturing and Repackaging facilities.

3.0 Responsibility

The Quality Unit is responsible for overseeing all elements outlined in this procedure. Production Managers, Production Supervisors, CSRs and Operations Management are responsible for participation in all outlined activities.

4.0 Safety Considerations

Care shall be exercised when unloading customer returned material to the warehouse. The material may have shifted or may not be properly secured to the pallet. Always wear facility required PPE including, but not limited to, safety glasses and steel toed boots.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or the community.

5.0 Materials/Equipment

- Copies of the following records:
  - Production Records/Logs
  - Customer Order Log (COL)
  - Raw Material Inventory
  - Film Check Log

Pouch Inventory
Carton Inventory

- Equipment/supplies for sampling products to be tested

6.0 Introduction

Giles Chemical, a division of Premier Magnesia, LLC is dedicated to manufacturing the highest quality products possible. Care is taken to insure that only the best leaves the premises. In the event that product does get shipped out which is of questionable quality, a product recall or withdrawal as outlined in this procedure, will be put into action.

Product recall is indicated when a product is manufactured that could represent a hazard to the consumer. A hazard could range from a labeling error to a serious health hazard. Our recall program will effectively remove that product from circulation.

Production dates, lot codes, and/or expiry dates are printed on the packaging of all products manufactured at Giles. All products that are shipped out have the production codes noted on the pick slips. In the event of a problem with any product, Giles will contact all our customers who received the product by phone and/or email and arrange for the product to be returned. We will insure that 100% of the product in question is returned or accounted for, either at the distributor level or at the end user level.

In the case of a serious health hazard Giles will issue a public warning via the news media, either on a local or regional basis to insure public safety. When required, Giles will involve the US Food and Drug Administration (FDA) or the Health Products and Food Branch of Health Canada (HPFB) for assistance.

7.0 Definitions

7.1 **Product Recall**

A Product Recall is initiated when the product may represent a health hazard to the consumer. The procedures implemented will effectively remove the product from circulation to prevent its consumption and/or use.

In certain instances, the FDA/HPFB may initiate a product recall, or take appropriate corrective action when our recalling performance is judged inadequate. In addition the FDA/HPFB may take enforcement actions either during or following the recall.

The Health Hazard Committee of the FDA is responsible for health hazard evaluations. The FDA is responsible for classifying the recalls (Class I, II or III) and taking the necessary steps.When a recall is initiated, the FDA/HPFB must be given a formal notification. The

FDA/HPFB monitors the effectiveness of the firm's recall actions and provides advice and direction.

7.1.1 Regulation Enforcement Agencies

FDA
US Food and Drug Administration
South East Region
Atlanta District
60 Eighth Street, NE
Atlanta GA 30309
Phone: 404-253-1293
Fax: 404-253-1201

HPFB
Health Products and Food Branch, Health Canada

Quebec Operational Centre
1001 St-Laurent Street West
Longueil, Quebec
J4K 1C7
Phone: 450-646-1353
Fax: 450-928-4455

Ontario Operational Centre
2301 Midland Avenue
Scarborough, Ontario
M1P 4R7
Phone: 416-973-1954
Fax: 416-973-1954

7.2 **Recall Classification**

When a product needs to be removed from the market, it must be assigned a classification. Recall classifications usually involve, but are not limited to, contamination, the presence of bacteria and/or a substance which may cause a potential allergic reaction. It is important to remember that the word "Recall" has a special legal, insurance and liability significance. It should be carefully used and only in situations where there has been possible violation of a Federal Statute or Regulation. Any conclusion must be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

A Health Hazard Evaluation and Recall Classification should be done to determine the procedures to take. The following points must be considered:

- Whether or not any disease or injuries have already occurred from the use of the product.
- Assessment of hazard to various segments of the population, e.g. children, surgical patients etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.
- Assessment of the likelihood of occurrence of hazard.

Where the problem is of a health and safety concern, you must consult with the FDA/HPFB to ensure that your action/decision is correct.

7.2.1 Types of Classifications

Class I: When there is an emergency situation involving removal from the market of products in which the consequences of use or exposure to the product are life threatening or involve a serious adverse health consequence.

Class II: When there is a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequence is remote.

Class III: When there is a situation in which the use of, or exposure to, the product is not likely to cause adverse health consequence. Example: Labeling violations

7.3 **Product Withdrawal**

A product withdrawal occurs when the company removes product from the market place and does not violate regulatory standards administered by the FDA/HPFB.

7.4 **Mock Recall**

In order to evaluate the product recall program, annual mock recalls shall be performed. Annual mock recalls will be performed ± 2 months of the previous year's mock recall. All information obtained during the mock recall will be documented. The mock recall file includes the name, address and telephone number of clients for the lot tested, production records, the inventory, and distribution of each lot distributed. Mock recalls are used to determine whether the recall procedure is capable of identifying and quickly controlling a given lot of potentially affected product and reconciling the quantities produced, quantities in inventory, and quantities distributed. A mock recall will identify potential problems and allow personnel to become familiar with recall procedures. If problems are identified in the recall procedures, they should be corrected. All corrective actions and deficiencies shall be documented in the *Recall/Withdrawal Report (Q12-PR-100-F013e).*

7.5 **Recall Team**

It is important to have a team responsible for traceability. The team is responsible for coordinating all aspects of the product recall. A recall coordinator is to be appointed and members of the recall team identified from various functional areas. Together the team will assist the Recall Coordinator in the event of a recall. All members must ensure that all procedures are carried out effectively and efficiently. The team is to receive appropriate training so that they understand their responsibilities. All team members must participate in annual mock recalls as part of the on-going training program. The *Recall Team Form (Q12-*

PR-100-F013d) shall be updated annually to ensure all names, contact phone numbers and responsibilities of team members and alternates are updated.

8.0 Recall Procedure

Once notified of a recall situation or a quality control finding or customer complaint that may result in a recall, immediately start the documentation and product tracking processes according to this procedure. Detailed record keeping of the incident keeps things organized, demonstrates due diligence (in a court of law) and results in more efficient and effective recall.

1st Phase – Investigation

1. CSR, Management or Recall Team member collects the following information:
   - Product and Quantity suspected to be involved
   - Lot number and expiry date, if applicable
   - Production dates and time
   - Production Records
   - BOL or Change Over for all materials shipped related to the product in question
   - Relevant QA/QC audit results
   - Whether the product has been or will be returned for evaluation
   - A detailed description of the incident to the extent known

   In the case of a customer complaint, gather relevant information from the customer about the nature of the product complaint using the *Customer Complaint Initiation* form *(Q12-PR-100-F019).*

2. Assemble the Recall Team to immediately conduct a product complaint investigation.

3. Following the *Corrective and Preventative Action (CAPA)* procedure *(Q12-PR-100-014)*, complete the *CAPA* form *(Q12-PR-100-F014)* document the information collected above and root causes of the incident and a corrective action plan.

4. Determine if any other product(s) may be potentially affected.

5. Outline an auditing strategy (document and/or physical) and begin the audit process.

6. Conduct a Health Hazard Evaluation and Recall Classification to determine the procedures to take.

   - **Product Recall:** Safety or Health Risk due to physical, chemical, biological or immunological.

   - **Product Withdrawal:** a quality related issue with the affected product(s).

2nd Phase – Tracking of Product

4 stages of product tracking exist:

I. Finished Product
II. Work-In-Progress
III. Raw Materials
IV. Packaging Materials

Traceability of all stages of manufacturing are maintained using one or all of the following: *Customer Order Log, Production Records/Logs and Raw Materials Inventory* (including packaging). All documents may be obtained from QA.

1. Utilizing the appropriate documents, determine the stage(s) that may be involved from in-coming raw material to distribution.

2. Verify the information collected during the investigation stage.

3. Expand auditing activities to include identified stages.

4. Immediately begin to segregate and quarantine the product(s) in question using *Quality Hold* placard(s) *(Q12-FM-100-002)* following the *Quarantine of Product* procedure *(Q12-PR-100-012).*

3rd Phase A – Product Recall

1. Re-assemble the Recall Team to review all the information gathered thus far.

2. Call and email the *Notification of Recall (Q12-PR-100-F013b)* to the affected customers.

3. Fax FDA/HPFB the *Recall/Withdrawal Action Log (Q12-PR-100-F013c)* within 24 hours of confirmed health and safety issues.

    - Ensure the following information:

        - Name and Product Code of the recalled product(s).
        - Production date(s) of the recalled product(s).
        - Reason for the recall.
        - Quantity of recalled product(s) distributed.
        - Quantity of recalled product(s) in inventory.
        - Area(s) of distribution and customers affected.

4. Coordinate, monitor and document the recovery of all affected product(s).

5. Conduct reconciliation on the total quantity of recalled product and affected product in inventory against the total quantity produced.

6. Randomly remove and submit samples of recalled product(s) to FDA/HPFB and QA laboratory for testing.

7. Collect test results and discuss the results/corrective actions with the FDA/HPFB and Recall Team.

3rd Phase B – Product Withdrawal

1. Re-assemble the Recall Team to review all the information gathered thus far.

2. Call and email the *Notification of Withdrawal (Q12-PR-100-F013a)* to the affected customers. Request that all product recovered be returned to Giles following *Returned Products* procedure *(Q13-PR-100-025)*

3. Coordinate, monitor and document the return of all affected product(s).

4. Conduct reconciliation on the total quantity of withdrawn product and affected product in inventory against the total quantity produced.

5. Collect test results and discuss the results/corrective actions with the Recall Team.

6. Submit CAPA to customer if requested.

Documentation of the current annual Mock Recall and Recall/Withdrawal will be kept in the Recall Manual maintained by the Quality Unit. Thereafter, the Quality Unit will file these documents in the cGMP Library for a minimum of four years.

9.0 Reference Documents

Notification of Withdrawal (Q12-PR-100-F013a)
Notification of Recall (Q12-PR-100-F013b)
Recall/Withdrawal Action Log (Q12-PR-100-F013c)
Recall Team Form (Q12-PR-100-F013d)
Recall/Withdrawal Report Template (Q12-PR-100-F013e)
Customer Complaint Initiation Form (Q12-PR-100-F019)
Corrective and Preventative Action System (Q12-PR-100-014)
Corrective and Preventative Action Form (Q12-PR-100-F014)

Quarantine of Product Procedure (Q12-PR-100-012)
Quality Hold Placard (Q12-FM-100-002)
Returned Products (Q13-PR-100-025)

10.0 Change Information

3 year review; updated header and owner.

Recall Flow Diagram