STANDARD OPERATING PROCEDURE (SOP)

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Title:	**RECALL PROCEDURE**	**SOP No.: ADM - 008**
Effective:	**01/15/2026**	**Rev.#/Date: Original**

1.0 PURPOSE

1.1 To describe the procedure for assuring a timely and effective removal of product from the market if a need for a product recall arises.

1.2 To ensure that a corrective action plan will be developed and implemented to prevent future product recall actions due to the same problem.

2.0 SCOPE

2.1 This procedure applies to the recall of all Company products distributed in the market by one of the following means:

2.1.1 The actual physical retrieval (removal, return, or recovery) from the customer.

2.1.2 Destruction at the customer's site.

2.1.3 Re-labeling or replacement of defective products without their physical return to the company.

2.2 This procedure does not apply to products removed from the market because of:

2.2.1 Stock rotation due to short expiration dating.

2.2.2 Stock correction due to excess quantity shipped to the customer.

2.2.3 Market withdrawal due to a decision by the company to no longer participate in a particular market segment.

3.0 DEFINITION (S):

3.1 **Recall -** means a firm's removal or correction of a marketed product that violates applicable laws and may pose a potential hazard to public health.

3.2 **Recall classification -** means the numerical designation, i.e., Class I, Class II, or Class III, assigned to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

3.2.1 Class I: A situation in which there is a reasonable probability that the use of the product will cause or has caused serious adverse health consequences or death.

3.2.2 Class II: A situation in which the use of the product may cause or did cause temporary or medically reversible adverse health consequences, or where the The probability of a serious health consequence is remote.

3.2.3 Class III: A situation in which use of the product is not likely to cause adverse health consequence.

4.0 POLICY:

It is the HAMIDA LABORATORY INC.'S policy to take its responsibilities to achieve by all means for and carrying out recalls within 8 hours in accordance with the regulatory requirements of the Food and Drugs Act (the Act), Food and Drug Regulations, including Division 5 (Drugs for Clinical Trials involving Human Subjects), and Natural Health Products Regulations regarding the recall of health products in the market.

5.0 RESPONSIBILITY

5.1 All Personnel with customer contact (including, but not limited to, Marketing/Customer Services) are responsible for assuring that all customer complaints are documented and processed as per the Complaint Procedure.
5.2 The Material Review Board is responsible for the formulation of the Recall Strategy and for the review and approval of appropriate corrective action. For potential recall actions, the Material Review Board is composed of management individuals from Manufacturing, Quality Assurance, and Marketing. The MRB will determine the type of recall.
5.3 Quality Assurance is responsible for the overall organizational response to the situation and for communications with the FDA and assembly and retention of the Product Recall Action Report.
5.4 Marketing/ Customer Services is responsible for customer notification of recall action and for the preparation of Recall Status Reports.

6.0 REFERENCE:

6.1 SOP ADM – 006 Customer Complaint Procedure
6.2 SOP ADM – 007 Returned Goods Procedure

7.0 EQUIPMENT / MATERIALS:

7.1 Complaint Action Report Form
7.2 Complaint Action Report Evaluation Form
7.3 Complaint Action Report Investigation Form
7.4 MRB Request and Report Form
7.5 Complaint Action Report Closure Form
7.6 Rapid Alert Notification of a Recall
7.7 Recall Team List

8.0 PROCEDURE

8.1 **Document Product Problems:** Problems with a product are recorded on a Customer Action Report and are processed as per Customer Complaint Procedure

8.2 **Halt Shipment of Suspected Product Lots:** If the problem or complaint is found to be of a serious nature, the QA Assurance immediately requests the Shipping Department to stop future shipments of the product lot until the course of action has been determined.

8.3 **Notify Sales Force:** The Marketing/ Customer Services notifies Sales Representatives of potential recall action.

8.4 **Collect MRB Perquisites:** The Director of QA/QC collects and documents information that will be required for the investigation and course of action determination, including:

8.4.1 Determination of the quantity of product lot remaining in inventory and inventory locations.
8.4.2 Determination of the total number of units distributed and the customer list, including the total number of units shipped to each and the date shipped.

8.5 **Conduct MRB:** The Director of QA/QC convenes a Material Review Board (MRB) to investigate the problem and determine the appropriate course of action.

8.6 **MRB Classifies Problem Seriousness:** If the problem or complaint relates to an impact on patient health, the FDA's nomenclature of seriousness is used to classify the type of recall.

8.7 **MRB Formulates Recall Strategy:** The Material Review Board reviews the information provided by QA/QC and determines an appropriate course of action (Recall Strategy) based on the seriousness of the problem or complaint and the individual circumstances. The Recall Strategy includes:

8.7.1 The extent of the recall. Note: a product recalled in one market does not necessarily result in a product recall in all markets to which the product has been shipped.
8.7.2 The need for public warnings.
8.7.3 The extent of effectiveness checks for the recall.

8.8 **If Needed, Report Recall Strategy to FDA:**

8.8.1 Once developed and MRB approved, the Recall Strategy is sent to the FDA within 8 hours if the recall is Class I or II. Class III recalls do not need to be reported.
8.8.2 The FDA reviews the adequacy of the Recall Strategy and recommends changes as appropriate.

8.9 **Implement the Recall Action:** Initiate the recall in accordance with the MRB-approved Recall Strategy. The initiation is not delayed pending the FDA's review of the Recall Strategy.

8.10 **Prepare Recall Notification Letter**

If a product recall is required, a recall notification letter is prepared with the input of QA, Regulatory Affairs, and Marketing. The recall notification letter contains the following information:

8.10.1 Description of the product involved.
8.10.2 Lot number(s) of product.
8.10.3 Request to stop using and/or stop distributing the product.
8.10.4 Brief description of the problem.
8.10.5 Request to notify the end user, in case of a product distributed through an intermediary/ distributor.
8.10.6 Instructions regarding what to do with the product.
8.10.7 Request for documented acknowledgment of receipt of notification.
8.10.8 Request for count of remaining product in customer's possession.
8.10.9 Name and title of person to contact for further information.

8.11 **Communicate the Recall:** Marketing/ Customer Services will communicate the recall to affected customers and Sales Representatives by phone, FAX, mailgram, or first class letter.

8.11.1 Letters and envelopes are marked conspicuously, preferably in bold red type, with the following text: **"PRODUCT RECALL (or CORRECTION)"**. The letter and the envelope should also be marked: **"URGENT"** for class I and II recalls and, when appropriate, class III recalls.
8.11.2 If phone calls are made, a letter is sent as a confirmation.

8.12 All customers and distributors involved in the recall action will be requested to provide a written confirmation of receipt of the recall notification. The recall notification letters can be sent by certified mail to facilitate the confirmation of receipt. Alternatively, Marketing can provide a confirmation form to the customer/distributor.

8.13 A second and, if necessary, third notification letter will be sent to customers who do not provide written confirmation of receipt of the recall notification. All reasonable efforts will be made to obtain this written confirmation.

8.14 **Monitor and Report Recall Status:**

8.14.1 The effectiveness of the recall will be monitored and reported on a routine basis by Marketing in Recall Status Reports.
8.14.2 Recall Status Reports are sent periodically to the appropriate branch of the FDA during the recall action if the recall is a Class I or II. The frequency of Recall Status Reports is determined by the relative urgency of the recall and is specified by the FDA in each recall case.

8.15 **Terminate Recall:** The recall action is terminated after receiving written permission from the FDA and not before all reasonable efforts have been made to retrieve and account for all affected product.

8.16 **Complete Product Recall Action Report:**

8.16.1 All applicable records are assembled by Quality Assurance to form a Product Recall Action Report. The report is reviewed and approved by Company Management.
8.16.2 The Product Recall Action Report will not be completed until corrective action plan has been completed and verified as effective.
8.16.3 The Product Recall Action Report is filed in the Quality Assurance department.

9.0 SAFETY / PRECAUTION (S) : N/A

10.0 ATTACHMENT (S) :

10.1 SOP Attachment – 10.4.1 Complaint Action Report Form
10.2 SOP Attachment – 10.4.2 Complaint Action Report Evaluation Form
10.3 SOP Attachment – 10.4.3 Complaint Action Report Investigation Form
10.4 SOP Attachment – 10.4.4 MRB Request and Report Form
10.5 SOP Attachment – 10.4.5 Complaint Action Report Closure Form
10.6 SOP Attachment – 10.5.2 Rapid Alert Notification of a Recall
10.7 SOP Attachment – 10.5.3 Recall Team List

11.0 DOCUMENT / REVISION HISTORY:

11.1 Issued by / date:

11.2 Rev. #/date Doc. Control # Description of Changes Originator/date