WORKING DRAFT AS OF 15 DEC 2023

FDA CIRCULAR
No: _____

SUBJECT : <u>Guidelines on the Recall of Health Products Regulated by the Food and Drug Administration</u>

I. RATIONALE

Republic Act (RA) No. 9711 otherwise known as the "Food and Drug Administration Act of 2009" and its Implementing Rules and Regulations (IRR) were enacted to establish an effective regulatory system for the authorization, registration, and monitoring of health products. Pursuant to Section 2 (i), Article II, Book I, the Food and Drug Administration (FDA) is mandated to require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report any incident that a product has caused or contributed to the death, serious illness or serious injury to a consumer, patient, or any person. Likewise, Section 5 (k) of the same law empowers the FDA, after due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, defective, ineffective, and/or grossly deceptive.

Part of the larger Post Marketing Surveillance (PMS) scheme of FDA is Product Recall, which enables the retrieval of imminently injurious, unsafe, defective, ineffective, and/or grossly deceptive health products from the distribution chain that may present a health hazard to the consumer or user. Hence, FDA Circular (FC) No. 2016-012 or the "Guidelines on Product Recall" was issued to prescribe guidelines on the conduct of Product Recall and outline the responsibilities of the FDA and Marketing Authorization Holder (MAH) on FDA-regulated products.

Since the implementation of this issuance, the globalization of trade, harmonization of standards, and the advent of electronic commerce facilitated the flow of goods. Meanwhile, the scope of products regulated by the FDA has since expanded and its processes digitized and updated to be at par with internationally-accepted practices. Regulatory oversight has since been more complex, and thusly urged regulatory authorities to seek strategic and more effective methods to safeguard public health and improve consumer awareness. The role of the industry as product stewards are more emphasized in this globalized and digital environment. The regulatory landscape of health products has changes significantly that the initially issued Guidelines on Product Recall needs to be revised. Thus, this Circular is hereby promulgated to create an updated framework for the recall of products, reflecting this evolving landscape, in pursuit of public health and safety.

II. OBJECTIVES

This Circular intends to establish a guideline on the recall of health products and effectively contribute in ensuring the safety and protection of the general public which present a substantial risk of injury, illness, and/or gross deception. Specifically, this Circular aims to:

A. Strengthen the recall system for health products under the jurisdiction of the FDA;

B. Specify the responsibilities and reporting obligations of the MAH in the conduct of product recall; and

C. Provide guidance to MAH in conducting effective recalls.

III. SCOPE

A. This shall cover all licensed manufacturers (including packers/repackers, refurbishers of medical devices), traders, distributors (importers, exporters, wholesalers) of health products, drug outlets (drugstore, pharmacies – community or institutional or boticas, retails outlets for non-prescription drugs (RONPD), and retailers of medical devices.

B. This shall apply to all authorized health products under the jurisdiction of the FDA, namely:

1. Human drug products, veterinary drug products, non-medicated veterinary products, medical devices for veterinary use, medical oxygen, traditional medicines, vaccine and biological products, herbal medicines, and home remedies-under the Center for Drug Regulation and Research (CDRR);

2. Pre-packaged processed food products, food supplements, food additives, and raw materials under the Center for Food Regulation and Research (CFRR);

3. Cosmetics, household/urban hazardous substances, household/urban pesticides, toys and childcare articles, and tobacco products under the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR);

4. Medical devices, health-related devices, radiation-emitting devices, and in-vitro diagnostic devices under the Center for Device Regulation, Radiation Health and Research (CDRRHR); and

5. Other products that may have an effect on health which require regulations as determined by the FDA.

IV. DEFINITION OF TERMS

For the purpose of implementing this Circular, the following terms are hereby defined for greater clarity:

A. Authorized Health Products refers to FDA-registered product that has a valid or active FDA authorization.

B. Center refers to the FDA Centers, namely: CDRR, CFRR, CCHUHSRR and CDRRHR.

C. Consumer refers to the individual member of the general public purchasing or using products for private purposes.

D. Establishment refers to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.

E. FDA-Ordered or **Mandatory Recall** refers to a recall ordered or directed by the FDA to MAH who does not initiate a recall.

F. Health Hazard Evaluation refers to the assessment of the product recall committee to the hazards presented by a product which determined the risk to the public and the necessary actions, including the commencement of a recall that may be undertaken to address the risk.

G. MAH-Initiated or **Voluntary Recall** refers to the prompted removal of health product from the supply chain, such as manufacturers, wholesalers, retailers, or retrieval from consumers or third-party users, initiated by the MAH.

H. Marketing Authorization Holder (MAH) refers to the company, corporate or legal entity that is responsible for all aspects of the product, including quality and compliance conditions of the marketing authorizations. The MAH may either be a manufacturer, trader, distributor, or retailer.

I. Product Recall Committee (PRC) refers to the authorized member from the different FDA Offices responsible for the investigation of triggers, review of product recall reports and strategies, and the general oversight of the recall system of health products.

J. Product Recall Resolution (PRR) refers to the formal statement of decision agreed at a duly convened meeting in which representatives exercise the power of voting on a comprehensive detailed of risk.

K. Recall refers to a method of retrieval of imminently injurious, unsafe, defective, ineffective, and/or grossly deceptive products from the distribution chain that may present a health hazard to the consumer or user.

L. Recall Strategy refers to a planned course of action to be taken in conducting a recall, which addresses the depth of recall, need for public warnings, extent of effectiveness checks, among others.

M. Risk Assessment refers to the process of harm and risk identification, analysis, and evaluation.

N. Risk Classification refers to the numerical designation to indicate the relative degree of health hazard presented by the product being recalled.

O. Risk Management Plan (RMP) refers to the document that contains a set of health product vigilance activities and interventions designed to identify, characterize, prevent, or minimize risks relating to health products, and the assessment of effectiveness of those interventions.

P. Supply Chain refers to the network that designs, manufactures, imports, distributes, and sells a product.

Q. Third-party User refers to a person other than the consumer who interacts with the product.

R. Traceability refers to the ability to follow the movement of a health product through specified stages of the supply chain such as, but not limited to, production, manufacturing, storage, distribution, retail outlets, and consumers.

V. GENERAL GUIDELINES

A. Only health products which adhere to safety, efficacy, and/or quality standards of the FDA, bearing the proper authorizations, may be placed in the Philippine market.

B. Health products bearing non-conformances to FDA standards on safety, efficacy, and/or quality which present a substantial risk of injury, illness or deception to the consumers and/or third-party users shall be subject to the recall system as stated in this Circular.

C. The FDA shall, in parallel, institute a PMS system that will allow the detection of triggers for recall, assessment of health hazards, and the recommendation and/or order of correction of products which present a substantial risk of injury, illness or deception to the consumers and/or third- party users.

D. The overall responsibility of conducting a recall lies with the MAH, including compliance with the required reporting and communication activities in accordance with this Circular. MAH are expected to be prepared in the event of a recall, having in place a system as part of their overall RMP, to detect triggers for recall, activate recall activities by trained and competent personnel, enable the

traceability of affected products, notify consumers and/or third-party users, and monitor and evaluate the effectiveness of recall.

E. When a decision to recall is made, the MAH shall notify the FDA and provide all available relevant information in accordance with this Circular. The information required to adequately identify the product and the product recall strategy (including the communication and effectiveness check plans) shall be submitted to the FDA.

F. All measures must be exhausted by the MAH to communicate the conduct of recall, the hazard and/or deficiency, and/or available remedies to consumers and/or third-party users. The FDA shall similarly announce recalls to consumers through the issuance of public health warning, alert, advisory, or other suitable means.

G. The FDA through the established Product Recall Committee (PRC) shall perform the oversight of the recalls in accordance with this Circular. The FDA PRC shall directly report to the Office of the Director General all activities, status, and actions taken on all recall as prescribed in this issuance.

H. In the event that the MAH fails to initiate a recall and/or adequately conduct a recall, the FDA PRC shall not be precluded from intervening and commencing further regulatory actions. The decisions provided by the FDA PRC may be appealed through the Office of the Director General in order to ensure public health and safety.

I. The FDA shall conduct the necessary inspections and audits to ensure the effectiveness of the product recall strategies of the MAH.

VI. SPECIFIC GUIDELINES

A. FDA Product Recall Committee

1. An FDA PRC shall be created in each Center by way of an FDA Personnel Order (FPO) composed, at the minimum, of the following members:

a. Director;
b. Division Chief, Licensing and Registration Division (LRD);
c. Division Chief, Product Research and Standards Development Division (PRSDD);
d. Senior Officer from the Common Services Laboratory (CSL);
e. Senior Officer from the Legal Services Support Center (LSSC);
f. Senior Officer from the Field Regulation Operations Office (FROO);
g. PRC Secretariat from PRSDD; and
h. Medical Doctor and Pharmacovigilance Staff, for CDRR.

2. The FDA PRC shall have the following roles, responsibilities, and functions:

a. Notify and submit recall report to the Office of the Director General and provide regular updates to the current status of the recall, actions taken, and progress made.

b. Manage the recall system of the products under the jurisdiction of their respective Centers;

c. Call upon the MAH to a conference to discuss recall reports and strategies to maximize recall effectiveness;

d. Process and review recall reports submitted by MAH, including the conduct of health hazard evaluation/risk assessment, classification of product recalls, development of recommendations to improve product recall strategies;

e. Oversee the review of triggers emanating from the PMS activities, perform the necessary health hazard evaluation/risk assessment, investigations, classify recalls, recommend the issuance of Product Recall Order (PRO) and other regulatory actions;

f. Develop and maintain a recall communication system with the assistance of all concerned FDA Centers and Offices.

g. Coordinate with the appropriate government agencies and international bodies for matters related to recalls, including the dissemination of safety alerts, as necessary;

h. Monitor and evaluate the compliance of on-going recalls in accordance with these Circular, and applicable rules and regulations;

i. Develop databases, forms, guidelines, and procedures consistent with this Circular; and

j. Perform other activities as deemed necessary for the effective implementation of this Circular.

B. Types of Recall

1. Product Recall is categorized based on the source of the decision to recall:

a. MAH-Initiated or Voluntary Recall, shall be done by the manufacturers, traders, and distributors of health products when they decided to and/or have withdrawn their product from any of the stages of the supply chain due to any safety and/or quality reason.

b. FDA-Ordered or Mandatory Recall, shall be done when the evaluation by the PRC shows that there is reason to believe that a health product can be imminently injurious, unsafe, defective, ineffective, and/or grossly deceptive, and when the MAH fails to initiate a recall.

C. Procedures on MAH-Initiated or Voluntary Recalls

1. **Reporting Obligations.** When the MAH decided to conduct a recall, the MAH shall immediately notify the FDA and provide all available relevant information.

    a. **Contents of the Report**

        i. **Identity of the MAH and Person Responsible for the Recall**, including name, complete address, and contact details;

        ii. **Identification of the Product**, including product name, description (dosage form, intended use or indication, shelf-life, expiration, type of packaging, product registration/notification number), batch/lot/consignment codes, quantity of products implicated, name and complete address of manufacturer, copy of commercial labeling (all labels, including inserts and tags);

        iii. **Reason for Recall**, including nature of problem/hazard, date and time at which the problem was identified, how the problem occurred and the dates it occurred, extent to which the problem affects all or a portion of the units/lots subject of recall, details of reported complaints/adverse events;

        iv. **Results of the Health Hazard Evaluation/Risk Assessment,** assessment of the problem and measures taken;

        v. **Recall Strategy**, including the depth of recall, scope of recall, communication plan, recall effectiveness strategy, proposed method for destroying or correcting the product;

        vi. **Distribution Details**, including description of distribution channels (name and address of distributors and retailers, quantity, and batch/lot/consignment codes of the products distributed); and

        vii. **Other Information**, including results of tests performed and other pertinent information that may be deemed necessary for inclusion in the report.

    b. **Timing of the Report.** The MAH shall notify the FDA no longer than twenty-four (24) hours from its decision to make a recall or from the time it receives information from their principal that a product they placed in the Philippine market is subject to a recall. The completeness of the information shall not in any way delay the submission of the Report. In all cases, the information contained in the Report shall be completed within ten (10) working days upon filing the report to the FDA through a supplemental filing.

c. Submission of Report Notification

i. The MAH shall file the report through the Food and Drug Action Center Office (FDAC) at info@fda.gov.ph, copy furnish the Office of the Director General at odg@fda.gov.ph.

d. Review and Classification of Recall

i. The FDA through the PRC of the concerned Center, shall conduct a review of the submitted report, evaluate possible health hazards, and recommend the classification of recall according to risk as follows:

(1) **Class I Recall** – product defects/conditions that are potentially life threatening or could result to severe health risk, health impairment or effects such as permanent damage to health or death, and/or grossly deceptive.

(2) **Class II Recall** – product defects/conditions that could cause poisoning or temporary/medically reversible adverse health problem or mistreatment or where probability of life threatening or severe health risks is remote.

(3) **Class III Recall** – product defects/conditions that may not pose a significant hazard to health, but recall may have been initiated for other reasons.

ii. The classification of the recall and any other directive to improve the recall strategy indicated in a PRR shall be discussed and communicated with the MAH through conference within forty-eight (48) hours from the receipt of the complete report. The FDA PRC shall not be precluded to further shorten or change timelines and to call upon the MAH in order to establish measures to mitigate risks to public health and safety.

2. Communication Requirements. Communication activities of product recalls shall be in accordance with the following rules:

a. The MAH shall ensure that all communications are clear, consistent, and accurate, such that intended consumers, third-party users, and other establishments in the supply chain understand the risk entailed in the product recall and the necessary steps they need to undertake to minimize such risk. Communications must be designed and written in a manner that does not downplay the hazard or in a language that makes an involved party less likely to participate in the recall.

b. A communication plan shall be submitted by the MAH as part of the product recall strategy. This shall include the following information:

i. Identification of communication channels; and

ii. Template documents, including press releases and recall notices wherein the minimum information required for any communication is provided in **Annex A**.

c. For Class I and II recalls, the MAH shall promptly notify all concerned parties (e.g., establishments involved in the supply chain, hospitals, outlets, and health facilities, healthcare professionals, consumers, third-party users, general public) on the product recall within twenty-four (24) hours at the time a risk of injury, illness, and/or gross deception is identified, copy furnishing the FDA.

For Class III recalls, the MAH shall promptly notify all concerned parties (as mentioned above) within seventy-two (72) hours.

d. The FDA shall issue the specific public health warnings, alerts, and other advisories in order to inform consumers and/or third-party users, and other establishment in the supply chain of violative products subject of recall, for the purposes of protecting public health and safety.

i. The FDA shall issue a public health warning for Class I and Class II Recalls.

ii. Public health warning for Class III Recalls shall be issued based on the health hazard evaluation and recommendations made by the FDA PRC.

iii. The FDA shall also endeavor to publish a list of product recalls, including the status of such recalls in a suitable and accessible platform.

3. **Recall Effectiveness Checks.** Activities to check the effectiveness of recalls shall be in accordance with the following rules:

a. MAH shall check and monitor the effectiveness of recalls to ensure that consumers, third-party users, and all establishments in the supply chain have received the communication and have acted or participated accordingly in the recall. Monitoring plans for effectiveness checks shall be part of the recall strategy.

b. A recall status report shall be submitted by the MAH to the concerned FDA PRC providing the updates consistent with the submitted monitoring plans for effectiveness. The frequency of reporting should be based on the product recall strategy of the MAH. The minimum information that shall form part of the recall status report is provided in **Annex B**.

c. The FDA shall perform activities, including but not limited to: inspection to

verify and monitor implementation of the recall; visits to consumers; third-party users; and other establishments in the supply chain to check dissemination of recall communications and level of recall participation; visits to MAH to follow-up corrective action; verification checks of disposal or destruction activities; analyses of samples; and other activities to check and verify the effectiveness of recalls, including its completion.

4. **Recall Completion and Termination.** The cessation of active recall operations based on recall completion and the subsequent recall termination shall be in accordance with the following rules:

   a. The MAH shall consider the following factors before making a decision to cease active recall operations:

      i. Objectives of the recall have been met;

      ii. There is a high level of confidence that a large proportion of affected consumers have received recall communications and have participated in the recall;

      iii. There are no longer any complaints and/or reports of injuries and/or illnesses;

      iv. There are appropriate levels of returns commensurate to the nature of the health hazard and risk; and

      v. 100% of identified distributors and retailers with affected products have participated and returned all their remaining stocks.

   b. The completion of a recall shall be reported to the FDA through a final status report. In the same submission, the MAH may request for the termination of the recall by complying with the procedures and the submission of documentation as provided in **Annex C**.

   c. A recall will be terminated by the FDA when the FDA PRC determines that all efforts have been made to remove or correct the health product in accordance with the recall strategy, and when the product subject to the recall has been removed and proper disposition has been made commensurate with the degree of hazard of the recalled product.

   d. In the event that a consumer or a member of the general public make a request on the information of completion and/or termination of a recall, such request shall be in adherence with the existing rules and regulations on the freedom of information.

5. **Recall Readiness.** MAH shall be prepared in the event of a product recall in accordance with the following rules:

a. MAH shall have a recall system in place as one of their risk management tools in the RMP. The recall system shall ensure that processes are in place to prevent product-related incidents that could lead to a recall, including the trigger detection, incident investigation, and health hazard evaluation/risk assessment.

b. The recall system shall allow the operation and activation of recall activities by a recall management team comprising of trained and authorized personnel which have competencies and roles in recall coordination and leadership, technical/engineering, operations, sales and marketing, risk management, legal, and communications.

c. The recall system shall incorporate procedures for the adequate monitoring and evaluation of the effectiveness of recall. It is recommended for MAH to conduct simulation of recall protocols, as resources would allow.

d. The MAH shall have a system in place that allows for the traceability of affected products and the notification of consumers, third-party users, and other establishments in the supply chain.

e. Mock recall shall be carried out on a yearly basis to assess the effectiveness recall system put in place. Any gaps found in the system during the mock recall shall be appropriately addressed so that operation can be activated immediately and promptly during an actual recall.

D. Procedures on FDA-Ordered or Mandatory Recalls

1. Triggers for product recall may result from Pharmacovigilance (PV), defective reports from reputable sources (e.g., ASEAN Post- Marketing Alert System or PMAS) and/or PMS activities of the FDA. The FDA shall follow its existing guidelines on product recall.

2. In instances where an MAH has not initiated a recall for an unsafe, defective, ineffective and/or grossly deceptive product, the FDA may issue a recall order to the MAH and follow procedures of its recall authority under Section 5(k) of RA No. 9711. If, after providing the MAH an opportunity to consult with the agency, and find that there is reasonable probability that the health product would cause serious illness or injury, the FDA may order the MAH of such product to initiate a recall. FDA-Ordered Recalls shall be subjected to the same rules as provided for in ***'Subsection C Procedures on MAH-Initiated or Voluntary Recalls'*** above.

3. In instances where the MAH refuses to conduct the mandatory recall or fails to effectively implement the agreed product recall strategy, the FDA shall perform the necessary regulatory actions, including the seizure, quarantine, destruction and/or disposal of the unsafe, defective, ineffective, and/or grossly deceptive product at the expense of the MAH.

E. Reconsideration on the Recall Order

1. The MAH may opt to request for administrative reconsideration of the recall order with the FDA Office of the Director General thru a formal request for reconsideration within fifteen (15) calendar days after receipt of a copy of the recall decision. Extension for filing of the request for reconsideration shall be entertained.

2. The applicant shall point specifically the findings or conclusions stipulated in the Recall Order which are not supported by facts, rules, or technical standards.

3. The FDA shall resolve the request for reconsideration within twenty (20) calendar days from receipt of the request for reconsideration. If the request for reconsideration is denied, the applicant may perfect an appeal before the Office of the Secretary of Health during the remainder of the period for appeal, reckoned from receipt of the resolution of denial. The procedure on appeal prescribed by the Department of Health or the Administrative Code of 1987 shall apply.

4. The FDA shall transmit the records of the product recall upon perfection of the appeal and order from the Department of Health.

5. The decision of the FDA or DOH may be subject to judicial review in accordance with the Administrative Code of 1987 and applicable laws.

6. The FDA shall publish and make available for public inspection of all final decisions of product recall, subject to the rules on Freedom of Information and Data Privacy.

7. For the above purpose, the FDA shall endeavor to prepare a register or compilation of those decisions or final orders or reports.

VII. PENALTY CLAUSE

Violations of any provision of this Circular, in line with the provisions of Republic Act No. 3720 and Republic Act No. 9711 and its IRR shall be a ground for the filing of appropriate administrative charges that could lead to the imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation, or revocation of any market authorization issued by FDA.

The following activities shall merit the imposition of penalties subject to the filing of appropriate administrative charges:

A. Failure to report a recall within the timelines provided in this Circular;
B. Failure to initiate and conduct a recall in accordance to the Product Recall Strategy approved by the FDA PRC;
C. Refusal to initiate and conduct a recall ordered by the FDA;
D. Failure to issue recall communications in accordance with the requirements and timelines provided in this Circular;

E. Failure to submit recall status reports in accordance with the requirements and timelines provided in this Circular;
F. Failure to conduct the disposition activity approved by the FDA;
G. The distribution, sale, resale, offer for sale, promotion, and/or advertisement of any recalled product; and
H. Other analogous grounds or causes as determined by the FDA.

VIII. MONITORING AND REVIEW

This Circular shall be reviewed and evaluated within three (3) years of its implementation to determine whether the policy's objectives, impact, and effectiveness are achieved.

IX. SEPARABILITY CLAUSE

If any part, term, of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term, or provision.

X. REPEALING CLAUSE

FDA Circular No. 2016-012, entitled, "Guidelines on Product Recall" is hereby repealed. Other related issuances inconsistent or contrary to the provisions of this Circular are hereby repealed accordingly.

XI. EFFECTIVITY

This Circular shall take effect after fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the Office of the National Administrative Register of the UP Law Center.

DR. SAMUEL A. ZACATE
Director General

ANNEX A

Minimum Information Required for Communications

Communications, including press releases and recall notices required under Section VI, Subsection C.2 shall contain the following information at the minimum:

A. Product details, including:

   1. Product name and brand name;
   2. Pack size;
   3. Registration/notification number; and
   4. Lot/batch/consignment codes

B. Reason for recall and associated health risk, including description of possible symptoms.

C. Warning to refrain from further distribution, dispensing, selling, and use of the product.

D. Advice to consumers and/or third-party users, including instructions on what to do in case of consumption, how to dispose or return the recalled product, whom and how to contact with inquiries about the recall.

E. The following information are also recommended to be included in recall communications:

   1. Product images and other assistive visuals to identify the product;
   2. A list of premises where the recalled product was previously made available; and
   3. Actions that have been taken by the MAH.

ANNEX B

Content of Recall Status Reports

Recall status reports required under Section VI, Subsection C.3. shall contain the following information at the minimum:

A. Name and number of establishments, date, and method of notification;

B. Name and number of establishments responding to the recall communication and quantity of health products on hand at the time it was received;

C. Name and number of establishments that did not respond (if needed, the identity of the non-responding consignees may be requested by the FDA);

D. Name and number of health products returned/accounted by each establishment communicated;

E. Results of effectiveness checks by MAH;

F. Estimated time of completion of the recall; and

G. How the health product is being quarantined;

In addition to the abovementioned information:

H. The initial status report shall contain details on the media announcement for Class I and II MAH – initiated recalls, Class III; and

I. The final status report shall contain:

1. Details on the final disposition of the recalled health products including destruction of warranted; and
2. Final inventory

ANNEX C

Procedure and Requirements for Recall Termination

A. Activities required and documents to be submitted to support the request for termination:

1. Where destruction is deemed necessary, whether actual health products or labelling materials

    a. Before the destruction, coordination with the FDA PRC shall be made to request for the presence of an FDA-authorized representative no later than one (1) week prior the activity.

    b. After the destruction activity, the MAH shall submit the following documents:

        i. Notarized final report on the final disposition of the recalled product;
        ii. Certificate of Destruction issued by a Department of Environment and Natural Resources (DENR) accredited third party waste treatment facility;
        iii. Photographs of the whole destruction activity covering even the transport of stocks meant for destruction; and,
        iv. Copy of the signed FDA inspection report of destruction, signed by all relevant officers during the actual destruction.

2. Where the health product is to be redressed:

    a. Before redressing, the MAH shall secure an approval from the FDA PRC. The MAH shall likewise coordinate with the FDA PRC to request for the inspection of the product to check its compliance with its registered specifications. The conduct of redressing shall be in accordance with applicable Good Manufacturing Practices (GMP) requirements.

    b. The following documents shall be submitted to support the request for termination:

        i. Notarized final report on the final disposition of the recalled product;
        ii. Copy of the signed FDA inspection report of redressing;
        iii. Submission of actual labelling material; and
        iv. Standard Operating Procedure (SOP) for redressing.

3. Where the MAH intends to return the affected health products to the country of origin:

    a. Before returning the products to the country of origin, the MAH shall secure approval from the FDA PRC. The MAH shall likewise coordinate with the FDA PRC to request for the presence of an FDA-authorized representative no later than one (1) week prior the inventory, sealing and packing of recalled products.

    b. The following documents shall be submitted to support the request for termination, within fifteen (15) calendar days upon receipt of concession:

i. Notarized final report on the final disposition of the recalled product;
ii. Copy of the signed FDA inspection report; and
iii. Documents indicating the fulfilment of the returned shipment.

B. After submission of the final status report and additional documentation, the FDA PRC shall conduct a review to determine that all efforts have been made to remove or correct the health product in accordance with the recall strategy, and when it is to assume that the product subject to the recall has been removed and proper disposition has been made commensurate with the degree of hazard of the recalled product.

1. If the FDA PRC determines that the recall has been completed, a termination letter to that effect shall be issued to the MAH indicating such. The FDA may deploy the FROO to further verify the status of recall completion. The FDA may further issue updates on the status of recalls on FDA PRC as deemed necessary.

2. If the FDA PRC determines that recall has not been satisfactorily completed, notice and further advice shall be provided to the MAH. The FDA shall not be precluded from undertaking any further regulatory action to ensure the effectiveness of recall.