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.