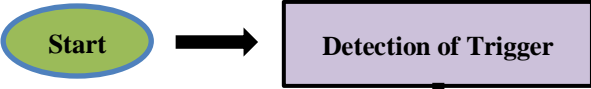
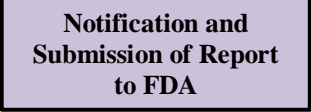

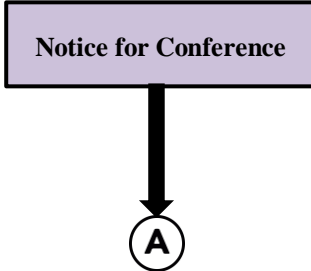
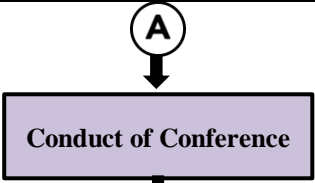
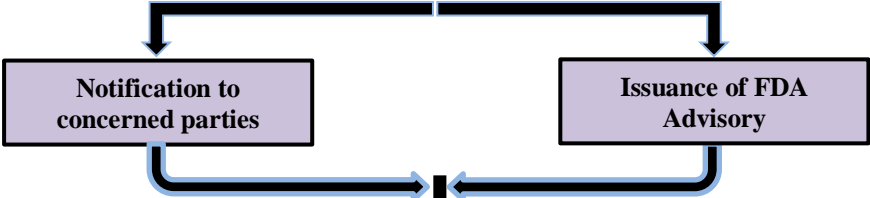
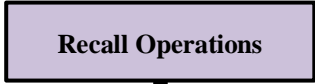

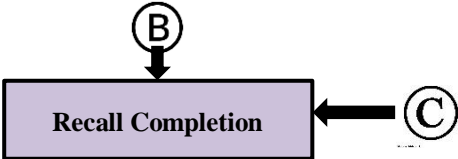
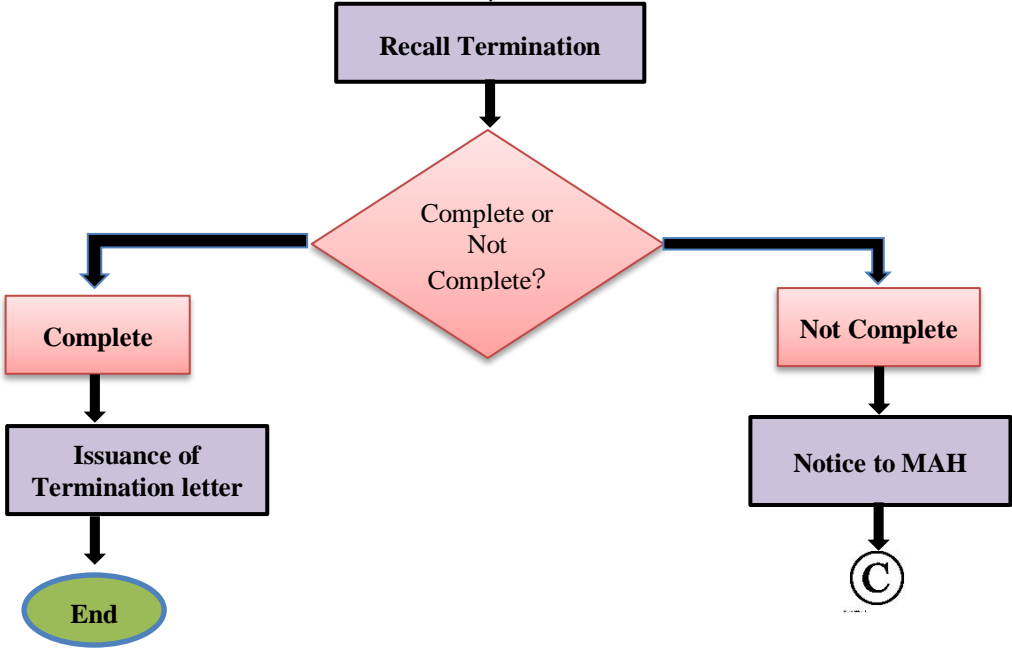


ANNEX A

Process Flow for MAH-Initiated or Voluntary Recall

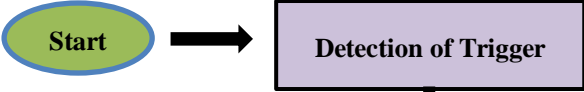

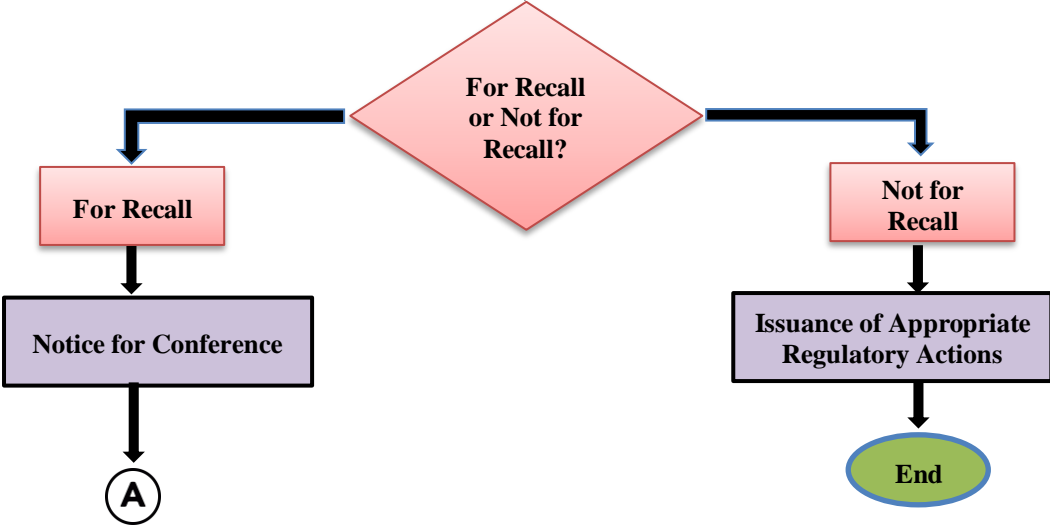
Responsible	Process	Interface
		<p>The consumer, non-consumer users, and all establishments in the supply chain shall discontinue further distribution, sale, and use of the affected batches of the health product upon detection of the trigger.</p>
MAH		<p>The MAH shall immediately notify the FDA and submit the initial report with all available relevant information within 24 hours from its detection of the trigger.</p>
FDA PRC		<p>The FDA PRC shall conduct a review of the submitted report, evaluate health hazards and recommend the classification of recall according to risk. A Product Recall Resolution (PRR) shall be prepared by the FDA PRC.</p>
FDA PRC		<p>After reviewing of the submitted report by the MAH, the FDA PRC shall call for a conference with the MAH to present the PRR within the timeline mentioned in Sec. VI.D.1.b 'Timing of the Report'.</p> <p>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.</p>

<p>FDA PRC and MAH</p>	 <p style="text-align: center;">A</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">Conduct of Conference</p>	<p>Conference with the MAH may be conducted through physical or virtual. Any other concerns about the classification and depth of the recall, and any directive to improve the recall strategy indicated in PRR shall be discussed.</p>
<p>FDA PRC and MAH</p>	 <p style="text-align: center;">↓</p>	<p>All communications shall be clear, consistent, and accurate that would understand the risk entailed in the product recall.</p> <p>The MAH shall promptly notify all affected parties on the product recall according to the classification of recalls, as follows: For Class I – within 24 hours; Class II – within 48 hours; and Class III – within 72 hours.</p> <p>Likewise, the FDA PRC shall issue an Advisory in order to inform the general public on the violative products subject for recall.</p>
<p>MAH</p>	 <p style="text-align: center;">↓</p>	<p>The MAH shall check and monitor the recall to ensure that consumers, non-consumer users, and all establishments in the supply chain have received the communication and have acted or participated accordingly in the recall.</p>
<p>FDA PRC and MAH</p>	 <p style="text-align: center;">↓</p> <p style="text-align: center;">B</p>	<p>A Recall Status Report shall be submitted by the MAH to the FDA PRC providing the updates consistent with the submitted monitoring plans for effectiveness.</p> <p>Likewise, the FDA PRC shall perform activities to check, verify, and monitor the implementation of the recall aligned with the regulatory standards.</p>

<p>MAH</p>		<p>The MAH shall ensure that the objectives of the recall based on the approved product recall strategies have been met prior to the cease of active recall. The completion of the recall shall be reported to the FDA through a Final Recall Status Report.</p> <p>In the same submission, the MAH may request the termination of the recall.</p>
<p>FDA PRC and MAH</p>		<p>The FDA PRC shall conduct a review of the submitted Final Recall Status Report and additional requirements to support the request for termination.</p> <p>A recall will be terminated by the FDA PRC when all efforts have been made to remove or correct the health product in accordance with the recall strategy.</p> <p>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 to its respective email address.</p> <p>If the FDA PRC determines that the recall has not been satisfactorily completed, a 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.</p>

ANNEX F

Process Flow for FDA-Ordered or Mandatory Recall

Responsible	Process	Interface
FDA		<p>The triggers for product recall may result from the different Postmarketing Surveillance (PMS) activities conducted by the FDA.</p>
FDA PRC		<p>Findings from the PMS activities which indicate a violation against applicable rules and regulations that suggest a substantial risk of injury, illness, and/or gross deception shall be evaluated by the FDA PRC to determine whether the product is for recall or not.</p>
FDA PRC		<p>Should a recommendation for recall be made, the FDA PRC shall prepare the Product Recall Resolution (PRR) and Notice of Conference to the MAH. The PRR shall contain details on the trigger and related evidence, the result of the health hazard evaluation, and the recall classification.</p> <p>Should a recall be found unnecessary, a PRR shall be prepared containing details on the trigger and related evidence, the result of the health hazard evaluation, and the recommendation to pursue other appropriate regulatory actions.</p>

Conference with the MAH may be conducted through physical or virtual. The agenda includes the **presentation of the PRR** by the FDA PRC and a **presentation of the recall strategy** by the MAH.

Agreement by both FDA PRC and MAH on the recall strategy shall be done. If both are **agreed**, the conduct of product recall shall be subject to the same rules as provided for in “**Subsection D. Procedures on MAH-Initiated or Voluntary Recalls**”. Otherwise, a **Product Recall Order (PRO)** be issued based on the recommendations of the FDA PRC.

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.

FDA PRC
and MAH

