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3 **FDA CIRCULAR**

4 **No:** \_\_\_\_\_

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7 **SUBJECT : Guidelines on the Recall of Health Products Regulated by the Food and**  
8 **Drug Administration**  
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11 **I. RATIONALE**

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

25  
26 Part of the larger Post Marketing Surveillance (PMS) scheme of FDA is Product Recall,  
27 which enables the retrieval of imminently injurious, unsafe, defective, ineffective, and/or  
28 grossly deceptive health products from the distribution chain that may present a health  
29 hazard to the consumer or user. Hence, FDA Circular (FC) No. 2016-012 or the  
30 “Guidelines on Product Recall” was issued to prescribe guidelines on the conduct of  
31 Product Recall and outline the responsibilities of the FDA and Marketing Authorization  
32 Holder (MAH) on FDA-regulated products.

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

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

- 7  
8 A. Strengthen the recall system for health products under the jurisdiction of the FDA;  
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10 B. Specify the responsibilities and reporting obligations of the MAH in the conduct of  
11 product recall; and  
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13 C. Provide guidance to MAH in conducting effective recalls.  
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16 **III. SCOPE**

- 17  
18 A. This shall cover all licensed manufacturers (including packers/repackers,  
19 refurbishers of medical devices), traders, distributors (importers, exporters,  
20 wholesalers) of health products, drug outlets (drugstore, pharmacies – community  
21 or institutional or boticas, retails outlets for non-prescription drugs (RONPD), and  
22 retailers of medical devices.  
23  
24 B. This shall apply to all authorized health products under the jurisdiction of the FDA,  
25 namely:  
26  
27 1. Human drug products, veterinary drug products, non-medicated veterinary  
28 products, medical devices for veterinary use, medical oxygen, traditional  
29 medicines, vaccine and biological products, herbal medicines, and home  
30 remedies-under the Center for Drug Regulation and Research (CDRR);  
31  
32 2. Pre-packaged processed food products, food supplements, food additives, and  
33 raw materials under the Center for Food Regulation and Research (CFRR);  
34  
35 3. Cosmetics, household/urban hazardous substances, household/urban pesticides,  
36 toys and childcare articles, and tobacco products under the Center for Cosmetics  
37 and Household/Urban Hazardous Substances Regulation and Research  
38 (CCHUHSRR);  
39  
40 4. Medical devices, health-related devices, radiation-emitting devices, and in-vitro  
41 diagnostic devices under the Center for Device Regulation, Radiation Health and  
42 Research (CDRRHR); and  
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44 5. Other products that may have an effect on health which require regulations as  
45 determined by the FDA.  
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48 **IV. DEFINITION OF TERMS**

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2 For the purpose of implementing this Circular, the following terms are hereby defined for  
3 greater clarity:  
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- 5       **A. Authorized Health Products** refers to FDA-registered product that has a valid or  
6 active FDA authorization.  
7
- 8       **B. Center** refers to the FDA Centers, namely: CDRR, CFRR, CCHUHSRR and  
9 CDRRHR.  
10
- 11       **C. Consumer** refers to the individual member of the general public purchasing or  
12 using products for private purposes.  
13
- 14       **D. Establishment** refers to a sole proprietorship, a partnership, a corporation, an  
15 institution, an association, or an organization engaged in the manufacture,  
16 importation, exportation, sale, offer for sale, distribution, donation, transfer, use,  
17 testing, promotion, advertising, or sponsorship of health products, including the  
18 facilities and installation needed for its activities.  
19
- 20       **E. FDA-Ordered or Mandatory Recall** refers to a recall ordered or directed by the  
21 FDA to MAH who does not initiate a recall.  
22
- 23       **F. Health Hazard Evaluation** refers to the assessment of the product recall  
24 committee to the hazards presented by a product which determined the risk to the  
25 public and the necessary actions, including the commencement of a recall that may  
26 be undertaken to address the risk.  
27
- 28       **G. MAH-Initiated or Voluntary Recall** refers to the prompted removal of health  
29 product from the supply chain, such as manufacturers, wholesalers, retailers, or  
30 retrieval from consumers or third-party users, initiated by the MAH.  
31
- 32       **H. Marketing Authorization Holder (MAH)** refers to the company, corporate or  
33 legal entity that is responsible for all aspects of the product, including quality and  
34 compliance conditions of the marketing authorizations. The MAH may either be a  
35 manufacturer, trader, distributor, or retailer.  
36
- 37       **I. Product Recall Committee (PRC)** refers to the authorized member from the  
38 different FDA Offices responsible for the investigation of triggers, review of  
39 product recall reports and strategies, and the general oversight of the recall system of  
40 health products.  
41
- 42       **J. Product Recall Resolution (PRR)** refers to the formal statement of decision  
43 agreed at a duly convened meeting in which representatives exercise the power of  
44 voting on a comprehensive detailed of risk.  
45
- 46       **K. Recall** refers to a method of retrieval of imminently injurious, unsafe, defective,  
47 ineffective, and/or grossly deceptive products from the distribution chain that may  
48 present a health hazard to the consumer or user.

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- 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.

28 **V. GENERAL GUIDELINES**

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- 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

1 traceability of affected products, notify consumers and/or third-party users, and  
2 monitor and evaluate the effectiveness of recall.  
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- 4 E. When a decision to recall is made, the MAH shall notify the FDA and provide all  
5 available relevant information in accordance with this Circular. The information  
6 required to adequately identify the product and the product recall strategy  
7 (including the communication and effectiveness check plans) shall be submitted to  
8 the FDA.  
9
- 10 F. All measures must be exhausted by the MAH to communicate the conduct of recall,  
11 the hazard and/or deficiency, and/or available remedies to consumers and/or third-  
12 party users. The FDA shall similarly announce recalls to consumers through the  
13 issuance of public health warning, alert, advisory, or other suitable means.  
14
- 15 G. The FDA through the established Product Recall Committee (PRC) shall perform  
16 the oversight of the recalls in accordance with this Circular. The FDA PRC shall directly  
17 report to the Office of the Director General all activities, status, and actions taken on all recall as  
18 prescribed in this issuance.  
19
- 20 H. In the event that the MAH fails to initiate a recall and/or adequately conduct a  
21 recall, the FDA PRC shall not be precluded from intervening and commencing  
22 further regulatory actions. The decisions provided by the FDA PRC may be  
23 appealed through the Office of the Director General in order to ensure public health  
24 and safety.  
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- 26 I. The FDA shall conduct the necessary inspections and audits to ensure the  
27 effectiveness of the product recall strategies of the MAH.  
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## 30 VI. SPECIFIC GUIDELINES 31

### 32 A. FDA Product Recall Committee 33

- 34 1. An FDA PRC shall be created in each Center by way of an FDA Personnel Order  
35 (FPO) composed, at the minimum, of the following members:  
36  
37 a. Director;  
38 b. Division Chief, Licensing and Registration Division (LRD);  
39 c. Division Chief, Product Research and Standards Development Division  
40 (PRSD);  
41 d. Senior Officer from the Common Services Laboratory (CSL);  
42 e. Senior Officer from the Legal Services Support Center (LSSC);  
43 f. Senior Officer from the Field Regulation Operations Office (FROO);  
44 g. PRC Secretariat from PRSD; and  
45 h. Medical Doctor and Pharmacovigilance Staff, for CDRR.  
46
- 47 2. The FDA PRC shall have the following roles, responsibilities, and functions:  
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- 1 a. Notify and submit recall report to the Office of the Director General and  
2 provide regular updates to the current status of the recall, actions taken, and  
3 progress made.  
4  
5 b. Manage the recall system of the products under the jurisdiction of their  
6 respective Centers;  
7  
8 c. Call upon the MAH to a conference to discuss recall reports and strategies to  
9 maximize recall effectiveness;  
10  
11 d. Process and review recall reports submitted by MAH, including the conduct  
12 of health hazard evaluation/risk assessment, classification of product recalls,  
13 development of recommendations to improve product recall strategies;  
14  
15 e. Oversee the review of triggers emanating from the PMS activities, perform  
16 the necessary health hazard evaluation/risk assessment, investigations,  
17 classify recalls, recommend the issuance of Product Recall Order (PRO) and  
18 other regulatory actions;  
19  
20 f. Develop and maintain a recall communication system with the assistance of  
21 all concerned FDA Centers and Offices.  
22  
23 g. Coordinate with the appropriate government agencies and international  
24 bodies for matters related to recalls, including the dissemination of safety  
25 alerts, as necessary;  
26  
27 h. Monitor and evaluate the compliance of on-going recalls in accordance with  
28 these Circular, and applicable rules and regulations;  
29  
30 i. Develop databases, forms, guidelines, and procedures consistent with this  
31 Circular; and  
32  
33 j. Perform other activities as deemed necessary for the effective  
34 implementation of this Circular.  
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## 36 **B. Types of Recall**

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

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40 **a. MAH-Initiated or Voluntary Recall**, shall be done by the manufacturers,  
41 traders, and distributors of health products when they decided to and/or have  
42 withdrawn their product from any of the stages of the supply chain due to  
43 any safety and/or quality reason.  
44  
45 **b. FDA-Ordered or Mandatory Recall**, shall be done when the evaluation by  
46 the PRC shows that there is reason to believe that a health product can be  
47 imminently injurious, unsafe, defective, ineffective, and/or grossly  
48 deceptive, and when the MAH fails to initiate a recall.

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## 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.





- 1 i. Identification of communication channels; and
- 2
- 3 ii. Template documents, including press releases and recall notices
- 4 wherein the minimum information required for any communication
- 5 is provided in **Annex A**.
- 6
- 7 c. For Class I and II recalls, the MAH shall promptly notify all concerned
- 8 parties (e.g., establishments involved in the supply chain, hospitals, outlets,
- 9 and health facilities, healthcare professionals, consumers, third-party users,
- 10 general public) on the product recall within twenty-four (24) hours at the
- 11 time a risk of injury, illness, and/or gross deception is identified, copy
- 12 furnishing the FDA.

13

14 For Class III recalls, the MAH shall promptly notify all concerned parties

15 (as mentioned above) within seventy-two (72) hours.

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- 17 d. The FDA shall issue the specific public health warnings, alerts, and other
- 18 advisories in order to inform consumers and/or third-party users, and other
- 19 establishment in the supply chain of violative products subject of recall, for
- 20 the purposes of protecting public health and safety.
- 21
- 22 i. The FDA shall issue a public health warning for Class I and Class II
- 23 Recalls.
- 24
- 25 ii. Public health warning for Class III Recalls shall be issued based on
- 26 the health hazard evaluation and recommendations made by the
- 27 FDA PRC.
- 28
- 29 iii. The FDA shall also endeavor to publish a list of product recalls,
- 30 including the status of such recalls in a suitable and accessible
- 31 platform.
- 32

33 **3 Recall Effectiveness Checks.** Activities to check the effectiveness of recalls shall

34 be in accordance with the following rules:

35

- 36 a. MAH shall check and monitor the effectiveness of recalls to ensure that
- 37 consumers, third-party users, and all establishments in the supply chain have
- 38 received the communication and have acted or participated accordingly in
- 39 the recall. Monitoring plans for effectiveness checks shall be part of the
- 40 recall strategy.
- 41
- 42 b. A recall status report shall be submitted by the MAH to the concerned FDA
- 43 PRC providing the updates consistent with the submitted monitoring plans
- 44 for effectiveness. The frequency of reporting should be based on the product
- 45 recall strategy of the MAH. The minimum information that shall form part
- 46 of the recall status report is provided in **Annex B**.
- 47
- 48 c. The FDA shall perform activities, including but not limited to: inspection to

1 verify and monitor implementation of the recall; visits to consumers; third-  
2 party users; and other establishments in the supply chain to check  
3 dissemination of recall communications and level of recall participation;  
4 visits to MAH to follow-up corrective action; verification checks of disposal  
5 or destruction activities; analyses of samples; and other activities to check  
6 and verify the effectiveness of recalls, including its completion.  
7

8 **4 Recall Completion and Termination.** The cessation of active recall operations  
9 based on recall completion and the subsequent recall termination shall be in  
10 accordance with the following rules:  
11

- 12 a. The MAH shall consider the following factors before making a decision to  
13 cease active recall operations:  
14
- 15 i. Objectives of the recall have been met;
  - 16
  - 17 ii. There is a high level of confidence that a large proportion of affected  
18 consumers have received recall communications and have  
19 participated in the recall;
  - 20
  - 21 iii. There are no longer any complaints and/or reports of injuries and/or  
22 illnesses;
  - 23
  - 24 iv. There are appropriate levels of returns commensurate to the nature  
25 of the health hazard and risk; and
  - 26
  - 27 v. 100% of identified distributors and retailers with affected products  
28 have participated and returned all their remaining stocks.  
29
- 30 b. The completion of a recall shall be reported to the FDA through a final  
31 status report. In the same submission, the MAH may request for the  
32 termination of the recall by complying with the procedures and the  
33 submission of documentation as provided in **Annex C**.  
34
- 35 c. A recall will be terminated by the FDA when the FDA PRC determines that  
36 all efforts have been made to remove or correct the health product in  
37 accordance with the recall strategy, and when the product subject to the  
38 recall has been removed and proper disposition has been made  
39 commensurate with the degree of hazard of the recalled product.  
40
- 41 d. In the event that a consumer or a member of the general public make a  
42 request on the information of completion and/or termination of a recall, such  
43 request shall be in adherence with the existing rules and regulations on the  
44 freedom of information.  
45

46 **5 Recall Readiness.** MAH shall be prepared in the event of a product recall in  
47 accordance with the following rules:  
48

- 1 a. MAH shall have a recall system in place as one of their risk management  
2 tools in the RMP. The recall system shall ensure that processes are in place to  
3 prevent product-related incidents that could lead to a recall, including the  
4 trigger detection, incident investigation, and health hazard evaluation/risk  
5 assessment.  
6  
7 b. The recall system shall allow the operation and activation of recall activities  
8 by a recall management team comprising of trained and authorized personnel  
9 which have competencies and roles in recall coordination and leadership,  
10 technical/engineering, operations, sales and marketing, risk management,  
11 legal, and communications.  
12  
13 c. The recall system shall incorporate procedures for the adequate monitoring  
14 and evaluation of the effectiveness of recall. It is recommended for MAH to  
15 conduct simulation of recall protocols, as resources would allow.  
16  
17 d. The MAH shall have a system in place that allows for the traceability of  
18 affected products and the notification of consumers, third-party users, and  
19 other establishments in the supply chain.  
20  
21 e. Mock recall shall be carried out on a yearly basis to assess the effectiveness  
22 recall system put in place. Any gaps found in the system during the mock  
23 recall shall be appropriately addressed so that operation can be activated  
24 immediately and promptly during an actual recall.  
25

#### 26 **D. Procedures on FDA-Ordered or Mandatory Recalls**

- 27  
28 1. Triggers for product recall may result from Pharmacovigilance (PV), defective  
29 reports from reputable sources (e.g., ASEAN Post- Marketing Alert System or  
30 PMAS) and/or PMS activities of the FDA. The FDA shall follow its existing  
31 guidelines on product recall.  
32  
33 2. In instances where an MAH has not initiated a recall for an unsafe, defective,  
34 ineffective and/or grossly deceptive product, the FDA may issue a recall order to  
35 the MAH and follow procedures of its recall authority under Section 5(k) of RA  
36 No. 9711. If, after providing the MAH an opportunity to consult with the agency,  
37 and find that there is reasonable probability that the health product would cause  
38 serious illness or injury, the FDA may order the MAH of such product to initiate a  
39 recall. FDA-Ordered Recalls shall be subjected to the same rules as provided for in  
40 *'Subsection C Procedures on MAH-Initiated or Voluntary Recalls'* above.  
41  
42 3. In instances where the MAH refuses to conduct the mandatory recall or fails to  
43 effectively implement the agreed product recall strategy, the FDA shall perform the  
44 necessary regulatory actions, including the seizure, quarantine, destruction and/or  
45 disposal of the unsafe, defective, ineffective, and/or grossly deceptive product at the  
46 expense of the MAH.  
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#### 48 **E. Reconsideration on the Recall Order**

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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

DRAFT