NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

RECALL, HANDLING AND DISPOSAL OF SUBSTANDARD AND FALSIFIED MEDICINAL PRODUCTS REGULATIONS

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 19th October, 2019).
PLEASE SEND ALL INPUT TO REGULATORYAFFAIRS@NAFDAC.GOV.NG

ARRANGEMENT OF SECTIONS

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honorable Minister of Health hereby makes the following Regulations:-

1. **Scope**

   These Regulations shall apply in the recall, handling, storage and disposal of substandard and falsified (SF) products manufactured, exported, imported, advertised, sold, distributed or used in Nigeria.

2. **Prohibition**

   No SF product shall be recalled, stored or disposed unless in accordance with the provisions of these Regulations.

3. **Reasons for recall**

   (1) The reasons for the recall of SF product shall include;
   - (a) Incorrect labeling of the product
   - (b) Incorrect formulation of a product
   - (c) Result of ongoing stability studies (unfavorable)
   - (d) Evident of poor storage and handling

   And any other reason as may be prescribed by the Agency.

4. **Initiation of voluntary recall**

   (1) A Certificate of Registration Holder shall initiate the voluntary recall of SF product.

   (2) The Certificate of Registration Holder shall notify the Agency in writing of the voluntary recall of the substandard products and shall include;
   - (a) product name,
   - (b) batch number,
   - (c) manufacturing date,
   - (d) expiry date,
   - (e) dosage form,
   - (f) identified defect,
   - (g) recall protocol
   - (h) any other information as may be prescribed by the Agency to make informed decision.

   (3) The Certificate of Registration Holder shall notify all the distributors of the product recall, reason for recall and the recall structures.

   (4) The Agency shall participate in the recall exercise.

   (5) A Certificate of Registration Holder shall bear the cost of the voluntary recall of Substandard and falsified product.

5. **Initiation of non-voluntary recall**
   (1) The Agency shall initiate the non-voluntary recall of SF product.
   (2) The Agency upon the establishment of the reason for recall of SF product shall notify the Certificate of Registration Holder. The notification shall include the details of the product shall include;
      (i) product name,
      (j) batch number,
      (k) manufacturing date,
      (l) expiry date,
      (m) dosage form,
      (n) identified defect,
   (3) Where there is no identifiable person responsible for the presence of the SF product in Nigeria, the Agency shall request any outlets and the public in possession of the SF product to the nearest office of the Agency.
   (4) A Certificate of Registration Holder shall bear the cost of the voluntary recall of Substandard and falsified product.

6. **Recall strategy**
   (1) The Certificate of Registration Holder shall prepare and obtain approval for the recall strategy.
   (2) The recall strategy shall include;
      (a) the duration for the recall.
      (b) the key personnel appointed to coordinate the recall and provide feedback to the Agency at intervals until the completion of the exercise.

7. **Notification and public announcement**
   Upon the Agency's approval for the recall of the SF product, the Agency shall make a public service announcement media at the expense of the Certificate of Registration Holder. The information shall also be hosted in the Agency's website.

8. **Submission of Recall report**
   (1) The Certificate of Registration Holder shall submit documented evidence of the recall at the end of the process.
   (2) The Agency shall assess the performance of the recall.

9. **Storage**
   (1) The recalled medicinal products shall be transferred to the Agency's storage facility and all inventories shall be reconciled.
   (2) The product shall be appropriately stacked and stored until disposal exercise is scheduled.

10. **Decision for disposal of SF**
    The Agency shall initiate the process of disposal when there is need for disposal of SF products.

11. **Planning for disposal of SF products**
    (1) For the purpose of effective disposal of the medicinal products, the following shall be identified;

(a) the quantities and dosage forms of the SF products,
(b) the respective disposal methods for all the identified dosage;
(c) the required human resources
(d) The location, space, equipment, materials and logistics for the volume of SF to be disposed.
(e) the estimated cost of the disposal exercise,

12. **Health and safety**
The Agency shall provide appropriate safety gears and sanitary provision on the site.

13. **Transfer of recalled SF products to disposal site**
The recalled SF products shall be transported to the disposal site in a secured manner and in the company of regulatory officer and security personnel.

14. **Sorting at the disposal site**
The recalled SF products shall be sorted at the disposal site according to the identified method of disposal as stated in Regulations 11 (1) (b)

15. **Disposal**
(1) The recalled and sorted medicinal products shall be disposed in accordance with the identified disposal method.
(2) The cost of the disposal of the SF product shall be borne by the Certificate of Registration Holder or any person found in possession of the SF product.

16. **Security**
The Agency shall provide security measures during the transportation, sorting and disposal of the recalled SF products.

17. **Penalty.**
(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :
(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N500,000 or to both such imprisonment and fine; and
(b) a body corporate, to a fine not exceeding N800, 000.
(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-
(a) director, manager, secretary or other similar officer of the body corporate; or
(b) partner or officer of the firm or
(c) trustee of the body concerned ;or
(d) person concerned in the management of the affairs of the association ;or
(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

18. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-

(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;

(b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, **"proceeds"** means any property derived or obtained, directly or indirectly, through the commission of the offence.

19. **Interpretations**

In these Regulations unless the context otherwise requires:

'Agency' means National Agency for Food and Drug Administration and Control

"Disposal" means the action or process of getting rid of any substandard and falsified medicine

Security Personnel: Anyone employed by government to protect from any form of hazards.

"**Recall**" means the process for withdrawing or removing of medicinal product from the distribution chain because it is either a substandard or falsified medicine. The recall might be initiated by the manufacturer, importer, distributor or the Agency.

"**Substandard products**" means approved medicinal products that fail to meet either their quality standards or their specifications, or both e.g. manufacturing error, expired or degraded.

"Falsified product" means medicinal products that deliberately/fraudulently misrepresent their identity, composition or source.

"Regulatory officer" means graduate trained by the Agency to perform regulatory functions.

'**Disposal**' means the action or process of getting rid or destruction of substandard and falsified medicinal products.

20. **Citation**

This Regulations shall be cited as the Recall, Disposal and Handling of Substandard and Falsified Medicinal Product Regulations

MADE at Abuja this …….day of ……..2019

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Inuwa Abdulkadir Esq
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)