FOOD AND DRUGS AUTHORITY

GUIDELINES FOR REPACKAGING OF FOOD PRODUCT(S)

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1. INTRODUCTION

In exercise of the powers conferred on the Food and Drugs Authority (FDA) by Part Seven, Section 148 of the Public Health Act, 2012, Act 851, these guidelines apply to all firms that repackage food products as well as persons or companies repackaging food from sources other than the manufacturer.

The purpose of these guidelines is to ensure that repackaging operations are carried out in accordance with current codes of Good Manufacturing Practices (cGMP) to guarantee that the quality and safety of repackaged food products are maintained or are the same as the bulk. These guidelines also provide manufacturers, importers and distributors with a comprehensive procedure for bringing their repackaging activities into compliance with Part Seven, Section 100 subsection 5 of the Public Health Act, 2012, Act 851.

This guideline is hereby promulgated for information, guidance and strict compliance by all concerned.

2. GLOSSARY

For the purpose of these guidelines the following definitions shall apply:

"Bulk" means the food product to be repackaged.

"Repackaging operation" means the transfer of food product from one container to another with similar labeling information as the bulk under controlled conditions to maintain the quality and safety.

"Repackaging containers" means receptors for receiving food products marked with similar information as the bulk food product to be repackaged.

"Adulteration" means a substance added to, or mixed or packed with, the food to increase its weight or reduce its quality or strength or to make it appear better or of greater value than it is.

3. REQUIREMENTS

3.1. GENERAL REQUIREMENTS

3.1.1. No firm or individual shall undertake repackaging operation without the authorization and supervision of the Food and Drugs Authority (FDA).

3.1.2. Repackaged food product shall not be adulterated; it shall be of the same quality as the bulk product.

3.1.3. The bulk product to be repackaged shall be wholesome, fit for human consumption and adequately labeled in accordance with the ***FDA Guidelines on Labelling of Pre-packaged Food Products.***

3.1.4. All repackaged food products shall be adequately labeled and the labeling information shall comply with the ***FDA Guidelines for Labeling of Pre-packaged Food Products***. The labeling information on all repackaged food product shall have the same substantive labeling declaration as the bulk product e.g. Best Before Date , Batch Number, List of ingredients, Net Weight amongst others.

3.1.5. The person or company carrying out the repackaging operation shall be legally responsible for all hazards of contamination or adulteration that may arise.

3.1.6. The repackaging facility shall be licensed in accordance with the ***Guidelines for Licensing of Manufacturing Facilities***

3.1.7. The facility within which the repackaging activity is carried out and the repackaging operation shall comply with current codes of Good Manufacturing Practices (cGMPs).

3.1.8. Personnel undertaking repackaging operations shall be medically certified by a District, Metropolitan or Municipal Assembly before the repackaging operation.

3.1.9. Equipment(s) for repackaging operations shall be calibrated where necessary, kept clean and maintained in accordance with the current codes of Good Manufacturing Practices (cGMPs).

3.2. SPECIFIC REQUIREMENTS

3.2.1. All applicants, requesting for supervision of repackaging operation by FDA shall submit a letter addressed to:

The Chief Executive Officer

Food and Drugs Authority

P. O. Box CT 2783

Cantonments-Accra

3.2.2. The letter shall state the product details i.e. product name(s), production and expiry date and batch number(s). Other information such as quantity of product to be repackaged, estimated period for the operation and reason(s) necessitating the repackaging operation shall be included in the letter.

3.2.3. Food and Drugs Authority (FDA) officials shall verify the quantity and reason(s) necessitating for the re-packaging operation. Documentation with respect to the wholesomeness of the bulk food product shall be requested and in the event of doubt of its safety and quality, samples shall be taken to the laboratory for verification or confirmation.

3.2.4. Food and Drugs Authority (FDA) officials shall evaluate the suitability of the repackaging area / facility for the repackaging operation to ascertain its compliance to current codes of Good Manufacturing Practices (cGMPs).

3.2.5. Food and Drugs Authority (FDA) officials shall evaluate re-packaging equipments, equipment cleaning and maintenance procedures to meet Current Codes of Good Manufacturing Practices [cGMPs]. All equipments shall be checked for calibration and previous records verified.

3.2.6. Food and Drugs Authority (FDA) officials shall inspect the personnel training records and medical certification issued by a District, Municipal or Metropolitan Assembly before the commencement of the re-packaging operation. Also personnel protective clothing as well as ancillary facilities shall be inspected to evaluate company's compliance to Current codes of Good Manufacturing Practices [cGMPs]

3.2.7. The client in agreement with Food and Drugs Authority (FDA) shall set a convenient date for the monitoring of the repackaging operation provided all requirements for the operations are met.

3.2.8. The company or individuals undertaking the repackaging operation shall ensure that repackaging containers are food grade and labeled with the same information as the bulk.

3.2.9. The company or individual shall be made to pay a supervision fee at the end of the monitoring. The invoice raised shall be on the basis of daily supervision.

4. TIMELINES

4.1. Authorization for repackaging of food products shall be granted by the FDA within a maximum period of fifteen (15) working days, provided all requirements stipulate in this guideline are met.

5. SANCTIONS

Any person or corporate body who contravenes or fails to comply with any of the requirements of these guidelines commits an offence and shall be liable to a fine in accordance with Part Seven, Section 148 subsection 4 & 5 of Public Health Act, 2012, (Act 851).

6. PENALTIES

Where non-adherence to this guideline results in exposure of consumers to a food safety risks, the FDA will impose an Administrative Charge in accordance with Section 148, Sub-Section 4 & 5 of the Public Health Act, 2012, Act 851.