FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE REGISTRATION OF PREPACKAGED FOODS

Document No.: FDA/FERD/GL-REG/2013/01
Date of First Adoption: 1st February 2013
Date of Issue: 1st March 2013
Version No.: 01

TABLE OF CONTENT

1. INTRODUCTION

In exercise of the powers conferred on the FDA by Public Health Act, 2012, Act 851, Part Seven, Section 148, these guidelines apply to the registration of prepackaged food in order to ensure the safety and quality of prepackaged food. These guidelines apply to all prepackaged food products that are:

a) Locally manufactured/produced

b) Imported

and are intended for human and animal consumption, distribution or to be offered for sale in Ghana.

The purpose of these guidelines is to provide guidance to prepackaged food manufacturers, producers and food importers on the requirements of the Food and Drugs Authority and the procedures by which prepackaged food shall be brought into compliance with Part Seven, Section 97 of the Public Health Act, 2012, Act 851.

These guidelines are hereby promulgated for information, guidance and strict compliance by all concerned.

2. GLOSSARY

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

"***Prepackaged food***" means a food substance packaged or made up in advance in a container, ready for offer to the consumer, or for catering purposes;

"***Label***" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a container of food.

*"**Non-compliant product**"* means any product that does not conform to relevant current specifications for the product in question.

"*Requirements*" are the criteria set down relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading;

"*Renewal*" means to make valid for a further period or extent, the validity of the registration of the prepackaged food for the period determined by the Board.

"***Deferred application***" means the application for registration of the product was deferred because the prepackaged food product does not comply with sections of the law or the General Labeling Rules. The registration is therefore put on hold until the product is reasonably brought into compliance with the law;

"***Rejected application***" means the application for registration was rejected because the prepackaged food was deemed unfit to be distributed, sold or used in the country for reasons which may include the product being found fake, adulterated or contaminated. The applicant may reapply for registration after corrective measures have been taken.

"Product variation" means formulation of the product has been altered (ie addition of ingredient, subtraction of ingredient or a major change in the formulation of the product).

3. REQUIREMENTS

3.3.1. REGISTRATION OF LOCALLY MANUFACTURED PREPACKAGED FOOD

An applicant shall, for the registration of locally manufactured prepackaged food:

3.1.1. Purchase and complete the under listed forms;

1. Application for licensing of Food Manufacturing Establishment (FDA/FM05/LOC/01);
2. Food Product Information (FDA/FM05/LOC/02); and
3. Premises Location Form (FDA/FM05/LOC/03).

3.1.2. Submit the above forms in addition to the following;

1. Business Registration Certificate;
2. Certificate of Analysis;(See Appendix 1)
3. Site Master File; (See Appendix 2)
4. Health/Food Handler's Test Certificate for Tuberculosis, Hepatitis A, typhoid and other communicable diseases for each worker on production line;
5. Documentation substantiating any claim on health, nutrition, superlative, comparative, etc. on the label;
6. Six (6) samples of each product as stated in sample schedule (see appendix 3);
7. A copy of the product label;
8. Total Registration fee as stated in the Food and Drugs Authority's Fee Schedule (non-refundable)

3.1.3. The application shall be addressed to

THE CHIEF EXECUTIVE

FOOD AND DRUGS AUTHORITY

P. O. BOX CT 2783

CANTONMENTS, ACCRA

3.2 REGISTRATION OF IMPORTED PREPACKAGED FOOD

An applicant shall, for the registration of imported prepackaged food:

3.2.1. Purchase and complete the under listed forms;

1. Imported Food Product Information Form (FDA/FM05/IM/02);
2. Warehouse Location Form (FDA/FM05/IM/03); and
3. Application for Registration as a Food Product Importer Form (FDA/FM05/IM/01) where necessary.
4. Application for Dry Food Storage Facility License (FDA/FID/FM-DFW/2013/07)
5. Application for Cold Food Storage Facility License (FDA/FSD/FM-CFW/2013/07)

3.2.2. Submit the above forms in addition to the following:

1. Business Registration Certificate;
2. Sanitary or Phytosanitary Certificate where applicable;
3. Certificate of Analysis;
4. Radiation certificate for the food product where applicable;
5. Documentation substantiating any claim on health, nutrition, superlative, comparative, etc. on the label; where applicable
6. Six (6) samples of each product as stated in sample schedule (see appendix .3):
7. A copy of the product label; and
8. Total Registration fee as stated in the Food and Drugs Authority's Fee Schedule. (non-refundable)

3.2.3. The application shall be addressed to

THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS, ACCRA

3.3 RENEWAL OF REGISTRATION

The Registration of a pre-packaged food is valid for three (3) years and must be renewed by the end of the third year. The registration shall be approved by the authority before any importation of the product, other than those used as samples for the purpose of this application, into the country.

3.3.1. REGISTRATION RENEWAL OF LOCALLY MANUFACTURED PREPACKAGED FOOD

An applicant shall, for the renewal of registration of a locally manufactured prepackaged food;

3.3.1.1. Complete a copy of Locally Manufactured Food Product Information form (FDA/FM05/LOC/02)

3.3.1.2. Submit the above form in addition to the following:

1. Certificate of Analysis; (only for product variations)
2. Copy of current Business Registration Certificate.
3. Copy of previous FDA Registration Certificate or Letter.
4. Two (2) samples of each product as stated in sample schedule (see appendix .3);
5. Registration renewal fee as stated in the Food and Drugs Authority's Fee Schedule (non-refundable)
6. Supporting documentation for any variations since the product was last registered.

3.3.1.3. The application shall be addressed to;

THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS, ACCRA

3.3.2. RENEWAL OF REGISTRATION FOR IMPORTED PREPACKAGED FOOD

An applicant shall, for the renewal of registration of imported prepackaged food:

3.3.2.1. Complete the Imported Food Product Information form (FDA/FM05/IM/02).

3.3.2.2. Submit the above form in addition to the following:

1. Certificate of Analysis (only for product variations)
2. Copy of current Business Registration Certificate.
3. Copy of previous FDA Registration Certificate or Letter.
4. Two (2) samples of each product as stated in sample schedule (see appendix .3);
5. Total Registration Renewal fee as stated in the Food and Drugs Authority's Fee Schedule (non-refundable)

   Supporting documentation for any variations since the product was last registered.

3.3.2.3. The application shall be addressed to;

THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS, ACCRA

3.3.2.4. Only company owners and/or competent company representatives with adequate knowledge of the company must complete the application form. Clearing agents are not allowed to complete and/or the application form.

3.3.2.5. Bulk/Group registration of products can only be considered if the categories and/or different food groups, which will be determined by the Authority, are more than fifty (50).

4. TIMELINES

4.1. Where all registration requirements have been met, the registration process shall take a maximum of thirty (30) working days from the date of submission of application.

4.2. Where the Food Drugs Authority is satisfied that there is the need to register a food product, it shall do so and issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Authority from time to time.

4.3. The Food and Drugs Authority may defer or reject an application.

4.4. Applicants shall respond or address any issues raised concerning their applications within a period of sixty (60) working days of issue of the notice.

4.5. Applications submitted but awaiting samples from the manufacturers/applicant to continue the registration process shall not exceed sixty (60) working days from the date of submission of the application.

4.6. If the Authority does not receive any response or samples within the period specified under 4.4 and 4.5, the applicant shall reapply for registration.

4.7. An appeal for the review of an application may be made in writing to the Authority within thirty (30) working days of issue of the rejection notice.

5. SANCTIONS

5.1. The Authority shall cancel, suspend, or withdraw the registration of a food product if:-

1. the grounds on which it was registered is later found to be false;
2. the circumstances under which it was registered no longer exist;
3. any of the provisions under which it was registered has been contravened; or
4. the premises in which the food product or part of the food product or premises, where it is manufactured, packaged or stored by or on behalf of the holder of the certificate of registration is unsuitable for the manufacture, packaging or storage of the food.

5.2. Where the registration of a food product is rejected or cancelled, the applicant shall ensure that the product does not find its way into trade.

6. PENALTIES

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

APPENDIX 3: SAMPLE SCHEDULE

LIQUIDS SIZE OF PACKAGING	QUANTITY OF SAMPLE(S)
1L – 2L	6
>2L – 10L	3
>10L	1

SOLIDS SIZE OF PACKAGING	QUANTITY OF SAMPLE(S)
600g – 2Kg	6
>2Kg – 10Kg	3
>10Kg	1

WINES AND HARD LIQUORS

LIQUIDS SIZE OF PACKAGING	QUANTITY OF SAMPLE(S)
2 L	4
>2L – 10L	2
>10L	1