



FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE REGISTRATION OF PREPACKAGED FOODS

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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 pre-packaged food in order to ensure the safety and quality of pre-packaged food. These guidelines apply to all pre-packaged 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 pre-packaged food manufacturers, producers and food importers on the requirements of the Food and Drugs Authority and the procedures by which pre-packaged 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:

“Pre-packaged 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, stencilled, 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 pre-packaged food for the period determined by the Board.

“Deferred application” means the application for registration of the product was deferred because the pre-packaged food product does not comply with sections of the law or the General Labelling 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 pre-packaged 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

3.1 REGISTRATION OF LOCALLY MANUFACTURED PREPACKAGED FOODS

An applicant shall, for the registration of locally manufactured pre-packaged food:

3.1.1. Purchase and complete the under listed Registration forms;

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

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

- Copy of Business Registration Certificate;
- Copy of Health/Food Handler’s Test Certificate for Tuberculosis, Hepatitis A, typhoid and other communicable diseases for each worker on production line;
- Certificate of Analysis for each product and variant where applicable (*Should be endorsed by an authorized officer*)
- A copy of the product label (**Model Label**);
- Samples of each product and variants where applicable (*see sample schedule in Appendix 1*)
 - a For Mock samples, submit Two (2) sample units
- Total Registration fee as stated in the Food and Drugs Authority’s Fee Schedule (**L.I.**) (non-refundable) – *see summary below*;
 - a Licensing of local food production premises (Renewable after every year)
 - Cottage Industry - GH¢50
 - Medium Scale Industry - GH¢300
 - Large Scale Industry - GH¢600
 - b Food Product Registration fee (Renewal after every 3 years)
 - Cottage Industry - GH¢150
 - Medium Scale Industry - GH¢450
 - Large Scale Industry - GH¢900
- Documentation substantiating any claim on health, nutrition, superlative, comparative, etc. on the label;

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 FOODS

An applicant shall, for the registration of imported pre-packaged food:

3.2.1. Purchase and complete the under listed Registration forms;

- Imported Food Product Information Form (**FDA/FM05/IM/02**);
- Warehouse Location Form (**FDA/FM05/IM/03**);
- Application for Registration as a Food Product Importer Form (**FDA/FM05/IM/01**).
- Application for Dry Food Storage Facility License (**FDA/FID/FMDFW/2013/07**) - *where applicable*
- Application for Cold Food Storage Facility License (**FDA/FSD/FMCFW/2013/07**) – *where applicable*

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

- Copy of Business Registration Certificate
- Sanitary or Phytosanitary Certificate where applicable;
- Certificate of Analysis for each product and variant where applicable (*Should be endorsed by an authorized officer*)
- Radiation certificate for the food product where applicable;
- A copy of the product label (**Model Label**)
- Samples of each product and variants where applicable (*see sample schedule in Appendix 1*)
 - For Mock samples, submit Two (2) sample units
- Total Registration fee as stated in the Food and Drugs Authority’s Fee Schedule (**L.I.**) (non-refundable) – *see summary below*;
 - a. Licensing of food storage facilities (Cold or Dry) (Renewable after every year)
 - (1) Small Scale - GH¢240
 - (2) Large Scale - GH¢600
 - b. Food Importers fee - GH¢400
 - c. Product Registration Fee - GH¢1800 per product (Renewable after every 3 years)

- d. Site verification fee:
 - \$20,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from outside Africa
 - \$10,000.00 for all products imported from Nigeria
 - \$10,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from West Africa
 - \$15,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from North, East, South and Central Africa
- Documentation substantiating any claim on health, nutrition, superlative, comparative, etc. on the label; where applicable

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. RENEWAL OF REGISTRATION OF LOCALLY MANUFACTURED PRE-PACKAGED FOOD

An applicant shall, for the renewal of registration of a locally manufactured pre-packaged food;

3.3.1.1. Purchase and complete the under listed Registration forms;

- Food Product Information (**FDA/FM05/LOC/02**);
- Application for licensing of Food Manufacturing Establishment (**FDA/FM05/LOC/01**) – *where the premises license is due for renewal*
- Premises Location Form (**FDA/FM05/LOC/03**) – *where the location of the premises is changed*

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

- Copy of Business Registration Certificate;
- Copy of Health/Food Handler’s Test Certificate for Tuberculosis, Hepatitis A, typhoid and other communicable diseases for each worker on production line;
- A copy of the product label (**Model Labels**)
- Samples of each product and variants where applicable (*see sample schedule in Appendix 1*)
- Total Registration fee as stated in the Food and Drugs Authority’s Fee Schedule(**L.I.**)(non-refundable) – *see summary below*;
 - a Licensing of local food production premises (Renewable after every year)
 - Cottage Industry - GH¢50
 - Medium Scale Industry - GH¢300
 - Large Scale Industry - GH¢600
 - c Food Product Registration fee (Renewal after every 3 years)
 - Cottage Industry - GH¢150
 - Medium Scale Industry - GH¢450
 - Large Scale Industry - GH¢900
- Documentation substantiating any claim on health, nutrition, superlative, comparative, etc. on the label;

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 pre-packaged food:

- 3.3.2.1 Purchase and complete the under listed Registration forms;
- Imported Food Product Information Form (**FDA/FM05/IM/02**);

- Warehouse Location Form (FDA/FM05/IM/03) - *where the warehouse location is changed*
- Application for Registration as a Food Product Importer Form (FDA/FM05/IM/01) - *where initial registration is due for renewal*
- Application for Dry Food Storage Facility License (FDA/FID/FMDFW/2013/07) - *where license is due for renewal*
- Application for Cold Food Storage Facility License (FDA/FSD/FMCFW/2013/07) - *where applicable & where license is due for renewal*

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

- Copy of Business Registration Certificate;
- A copy of the product label (**Model Label**);
- Samples of each product and variants where applicable (*see sample schedule in Appendix I*)
- Total Registration fee as stated in the Food and Drugs Authority's Fee Schedule (**L.I.**) (non-refundable) – *see summary below*;
 - a. Licensing of food storage facilities (Cold or Dry) (Renewable after every year)

Small Scale	-	GH¢ 240
Large Scale	-	GH ¢ 600
 - b. Food Importers fee - GH¢ 400
 - c. Product Registration Fee - GH¢1800 per product (Renewable after every 3 years)
 - d. Site verification fee:
 - \$20,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from outside Africa
 - \$10,000.00 for all products imported from Nigeria
 - \$10,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from West Africa
 - \$15,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from North, East, South and Central Africa
- Copy of previous FDA Registration Certificate or Letter.
- 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. All documents to be submitted for registration must be comb-bound

3.3.2.5 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.

3.3.2.6 Model labels submitted solely for evaluation attract a fee of GH¢ 50.00

3.3.2.7 Name Search for products

- Up to 5 products - GH¢50
- 5 to 10 products - GH¢100
- More than 10 products - GH¢200

3.3.2.8 All submissions made to the FDA should always be accompanied by a cover letter. E.g. Submission of additional samples, revised certificate of analysis, variants, payments, responses etc

3.3.2.5. Bulk 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 1 : SAMPLE SCHEDULE

New application (Liquids)

Liquid size packaging	AMOUNT
SMALLER VOLUMES	
1ml-10ml	2L
>100ml -250ml	3L
>250ml-500ml	4L
>500ml-999ml	5L
larger volumes	QUANTITY OF SAMPLE(S)
1L-2L	6
>2L-10L	3
>10L	1

Renewal (Liquids)

Liquid size packaging	AMOUNT
1ml-100ml	1L
>100ml-250ml	1.5L
>250ml-500ml	2L
>500ml-999ml	2.5L

New (Solids)

Solid Size packaging	Amount
1g-100g	1kg
>100g-249g	2kg
>250g-599g	3kg
Larger weights	QUANTITY OF SAMPLE(S)
600g-2kg	6

>2kg-10kg	3
>10kg	1

Renewal (Solids)

Solid Size packaging	Amount
1g-100g	0.5kg
>100g-250g	1kg
>250g-599g	1.5kg
Larger weights	QUANTITY OF SAMPLE(S)
600g-2kg	3
>2kg-10kg	2
>10kg	1

WINES AND HARD LIQUORS

LIQUIDS SIZE OF PACKAGING	QUANTITY OF SAMPLE(S)
750ML-2L	4
>2L-10L	2
>10L	1

Exemptions

Teas in packs- 10 pack of each variant where applicable.

Toffees – 6 packs each

Spices & Seasoning in sachets- 300g