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| Document Type: **Form** | | | Doc. No | : FDISM/FDIC/FOM/007 |
|  | Title: **Application form for Good Manufacturing Practice inspection for food product manufacturing facilities** | | Revision Number | : 0 |
| Revision Date: | : 30/10/2022 |
| Effective Date | : 30/12/2022 |
| Review Due Date | : 29/12/2025 |
| Ref Doc. | : FDISM/FDIC/GDL/004 |

**Applicant to fill the following sections**

1. **Particulars of the Applicant**

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Telephone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Particulars of Manufacturing Site to be Inspected**

Name of site\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Address (if different from 1. above)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tel\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Note****: Separate application to be filled in for each individual site*

1. **Contact Person on Site**

Name of contact person\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Authorized Representative/Agent in Rwanda**

Name of Local Technical Representative\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Type of Food product risk categories**

Type of food product (*double click to check applicable box)*

1. High risk foods for special nutritional purposes ☐
2. High risk foods for general purpose ☐
3. Low risk foods ☐
4. **List of the products to be registered**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Brand Name | Common Name | Form of the physical characteristic of the food (e.g: Solid, liquid etc) | Packaging unit(s) in weigh or volume or number | Packaging container(e.g:Bottle,Box, sachet etc) |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Registration of Products in Rwanda**

Have you registered any products in Rwanda YES ☐ NO ☐

Have you submitted product dossier for registration from the production line(s) applied for inspection? YES ☐ NO ☐ (If "YES", list of the products in the table below)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Brand Name | Common Name | Form of the physical characteristic of the food (e.g: Solid, liquid etc) | Packaging unit(s) in weigh or volume or number | Packaging container(e.g:Bottle,Box, sachet etc) |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Inspection Applied for (Double click to check applicable box)**

☐ First Inspection

☐ Routine Inspection (state previous inspection dates ………………*DD/MM/YYYY*)

☐ Re-inspection (after failure)

☐ Other *(please specify)* …………………………………………………………….

1. **Major Site Changes Since Last Inspection**

Provide summary of changes to personnel, equipment, buildings, specifications, computer systems, products (type, range or category), suppliers and contractors since last inspection, below or as an Attachment to this form.

………………………………………………………………………………………………………

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**Production Lines to be Inspected** *(Please tick or fill in the applicable boxes)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Yes | No | Building Block name/Number | Number of production lines |
| 1 | **MANUFACTURING OPERATIONS** |  |  |  |  |
| 1.1. | **High risk Foods for special nutritional purposes** |  |  |  |  |
|  | A. Infant formulae and follow-up formulae |  |  |  |  |
|  | B. Complementary food for infants and young children |  |  |  |  |
|  | C. Foods intended for special medical purposes |  |  |  |  |
|  | D. Formula foods for use in weight control diets |  |  |  |  |
|  | E. Food supplements |  |  |  |  |
|  | e.i. Vitamins and Minerals |  |  |  |  |
|  | e. ii. Amino acids |  |  |  |  |
|  | e.iii. Essential Fatty acids |  |  |  |  |
|  | e. iv. Plant, plant extracts and other herbal based supplement |  |  |  |  |
|  | e.v.Enzymes and other metabolites |  |  |  |  |
|  | e.vi.Prebiotics |  |  |  |  |
|  | e.vii.Probiotics |  |  |  |  |
|  | e.viii.Animal products and animal extracts |  |  |  |  |
|  | e.ix.Protein Concentrates |  |  |  |  |
|  | Other and specify |  | |  |  |
| 1.2. | **High risk Food for general purpose** |  |  |  |  |
|  | A. Milk and milk products |  |  |  |  |
|  | a.i.Processed liquid milk |  |  |  |  |
|  | a.ii.Flavoured dairy-based drinks |  |  |  |  |
|  | a.iii.Fermented and renneted milk products |  |  |  |  |
|  | a.iv .Condensed milk and evaporated milk |  |  |  |  |
|  | a.v.Cream and cream analogue |  |  |  |  |
|  | a.vi. Milk powder and cream powder |  |  |  |  |
|  | a.vii.Cheese and analogues |  |  |  |  |
|  | a.viii.Dairy-based desserts |  |  |  |  |
|  | a.ix.Butter |  |  |  |  |
|  | a.x. Ghee |  |  |  |  |
|  | B.Meat and meat products |  |  |  |  |
|  | b.i.Processed meat, poultry and game products |  |  |  |  |
|  | b.ii.Processed comminuted meat, poultry and game products |  |  |  |  |
|  | b.iii.Edible casing |  |  |  |  |
|  | C. Fish and Fish products including molluscs, crustaceans and echinoderms |  |  |  |  |
|  | c.i.Processed fish and fish products including molluscs, crustaceans and echinoderms |  |  |  |  |
|  | c.ii.Semi-preserved fish and fish products including molluscs, crustaceans and echinoderms |  |  |  |  |
|  | c.iii.Fully preserved, canned or fermented fish and fish products including molluscs, crustaceans and echinoderms |  |  |  |  |
|  | D. Eggs and egg products |  |  |  |  |
|  | d.i. Eggs products |  |  |  |  |
|  | d.ii. Preserved eggs |  |  |  |  |
|  | d.iii.Egg-based desserts |  |  |  |  |
|  | E. Spices ,soup, sauces, salads and proteins products |  |  |  |  |
|  | e.i.Herbs,spices,seasonings and condiments |  |  |  |  |
|  | e. ii. Mustards |  |  |  |  |
|  | e.iii. Soups and broths |  |  |  |  |
|  | e. iv. Sauces and like products |  |  |  |  |
|  | e.v.Salads |  |  |  |  |
|  | e.vi.Yeast and similar products |  |  |  |  |
|  | e.viii.Soybean products |  |  |  |  |
|  | e. viii. Other protein products |  |  |  |  |
|  | F. Processed vegetables and vegetable products |  |  |  |  |
|  | f.i.Dried vegetables |  |  |  |  |
|  | f.ii.Vegetables in vinegar,oil,brine or soy sauce |  |  |  |  |
|  | f.iii. Fermented vegetable products |  |  |  |  |
|  | f.vi. Cooked,blached or fried vegetables |  |  |  |  |
|  | G. Ready to eat savouries |  |  |  |  |
|  | g.i. Processed nuts and nuts products |  |  |  |  |
|  | g.ii.Desicated nuts |  |  |  |  |
|  | H. Composite foods |  |  |  |  |
|  | I. Potable Water(mineral/drinking water) |  |  |  |  |
|  | J. Herbal tea |  |  |  |  |
|  | Other and specify |  | |  |  |
| 1.3. | **Low risk food** |  |  |  |  |
|  | A .Fats and oil, and fat emulsions |  |  |  |  |
|  | a.i.Vegetable oil and fat |  |  |  |  |
|  | a.ii.Fat emulsions containing less than 80% |  |  |  |  |
|  | a.iii.Fat emulsion containing more than 80% |  |  |  |  |
|  | a.iv Animal fat |  |  |  |  |
|  | a.v.Fat-based desserts |  |  |  |  |
|  | B. Edible ices, including sherbet and sorbet |  |  |  |  |
|  | C.Flours |  |  |  |  |
|  | c.i.Maize Flour |  |  |  |  |
|  | c.ii.Wheat Flour |  |  |  |  |
|  | c.iii Sorghum Flour |  |  |  |  |
|  | c.iv.Rice Flour |  |  |  |  |
|  | c.v mixed Flour |  |  |  |  |
|  | c.vi Other type of flour and specify |  |  |  |  |
|  | D.Processed Fruits and fruits products |  |  |  |  |
|  | d.i. Dried fruit |  |  |  |  |
|  | d.ii. Fruits in vinegar, oil or brine canned or bottled fruit |  |  |  |  |
|  | d.iii.Jams,jellies,marmalades,fruits-based spreads |  |  |  |  |
|  | d.iv. Fruit preparations |  |  |  |  |
|  | d.v.Fruits-based desserts |  |  |  |  |
|  | d.vi. Fermented fruit products |  |  |  |  |
|  | d.vii. Cooked or fried fruit |  |  |  |  |
|  | d.viii.Fruits juices and nectars and their concentrates |  |  |  |  |
|  | E. Confectionaries |  |  |  |  |
|  | e.i. Hard and soft candy |  |  |  |  |
|  | e. ii. Chewing gums |  |  |  |  |
|  | F. Coffee,Tea,Coccoa and their products |  |  |  |  |
|  | f.i.Coffee |  |  |  |  |
|  | f.ii.Coffee products |  |  |  |  |
|  | f.iii. Tea |  |  |  |  |
|  | f.iv.Coccoa |  |  |  |  |
|  | f.v.Coccoa products |  |  |  |  |
|  | G. Cereals and cereal products |  |  |  |  |
|  | g.i Whole, broken or flaked grains |  |  |  |  |
|  | g.ii.Cereal starches |  |  |  |  |
|  | g.iii.Breakfast cereals including rolled oats |  |  |  |  |
|  | g. iv. Pastas and noodles and like products |  |  |  |  |
|  | g.v.Cereal and starch based desserts |  |  |  |  |
|  | g.vi Pre-cooked or processed rice products |  |  |  |  |
|  | H. Bakery wares |  |  |  |  |
|  | h.i.Breads,cake,biscuits,chappatti,crackers,cookies |  |  |  |  |
|  | h.ii.Fine bakery wares and mixes |  |  |  |  |
|  | I. Sweeteners including Honey |  |  |  |  |
|  | i.i. Sugar |  |  |  |  |
|  | i.ii. Other sugars and syrups |  |  |  |  |
|  | i.iii. Honey |  |  |  |  |
|  | i.iv.Table-top sweeteners |  |  |  |  |
|  | J.Non Alcoholic Beverages |  |  |  |  |
|  | j.i.Soft drinks |  |  |  |  |
|  | j.ii.Cereal based drinks |  |  |  |  |
|  | j.iii.Ice rallies |  |  |  |  |
|  | j.iv.Powdered drinks |  |  |  |  |
|  | K. Alcoholic beverages |  |  |  |  |
|  | k.i. Portable Spirts and liquors |  |  |  |  |
|  | k. ii. Wines and Rosella alcoholic drink |  |  |  |  |
|  | k.iii. Cider and Perry, Mead alcoholic drinks |  |  |  |  |
|  | k.iv.Cereal based alcoholic beverages |  |  |  |  |
|  | k.v.Non cereal based alcoholic beverages, Specify |  |  |  |  |
|  | L.Salt and salt substitutes |  |  |  |  |
|  | M. Vinegars |  |  |  |  |
|  | Other and specify |  | |  |  |
| 2 | **PACKAGING OPERATIONS** |  |  |  |  |
|  | 2.i. specify the product |  | |  |  |

1. **Declaration**

*I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site(s).* *I also commit to welcome the Rwanda FDA GMP inspectors for the inspection.*

Signature of applicant……………………………. Date……………………………

Name……………………………………….. Designation..............................

***Notes****:*

*1.Please submit a copy of the current Site Master File together with this application (refer to Guideline on preparation of a Site Master File)*

*2. Submit the completed application together with proof of payment of the appropriate fees, to the Director General Rwanda Food and Drugs Authority.*

|  |  |  |
| --- | --- | --- |
| *This box is to be completed by Rwanda FDA official only* | | |
| **Inspection Reference Number**: | | |
| *Assigned to:* | *Lead GMP Inspector* | *Team GMP Inspector(s)* |
| *Name* |  |  |
| *Assigned by:*  *Name* | *Title: signature: Date:* | |