



*Your Well-being, Our Priority.*

# **REQUIREMENTS FOR REGULATED PRODUCTS**

# OUTLINE



Mandate of FDA



Food Product  
Registration



Food Facility License



Site Verification



Food Service  
Establishment



Drugs, Veterinary and  
Herbal Medicines



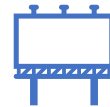
Cosmetics, Household  
Chemicals,



Medical Devices



Facility Licensing and  
Import Permit



Advertisements

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# FDA CORE MANDATE



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## A National Regulatory Body

- Food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, blood and blood products as well as the conduct of clinical trials protocols.

## Ensure Public Health Safety

- Registration
- Inspection
- Market Surveillances
- Intelligence
- Advertisement
- Testing



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# MANUFACTURING FACILITY LICENSE REQUIREMENTS - FOOD



Cover Letter

Completed Application Forms

Copy of Business Registration Certificate

Heath Certificate of Food Handlers

Layout of Facility



Application Fees:

- Cottage Industry - GH¢ 100.00
- Small Scale Industry - GH¢ 200.00
- Medium Scale Industry- GH¢ 300.00
- Large Scale Industry - GH¢ 700.00

# COLD & DRY STORAGE FACILITY LICENSE REQUIREMENTS



Application Fees:

- Small Scale - GH¢ 240.00
- Medium Scale - GH¢ 500.00
- Large Scale - GH¢ 800.00

# SITE VERIFICATIONS - FOOD



\$10,500.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from outside Africa



\$8,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from Africa



\$6,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from West Africa and for all products imported from Nigeria

**NB: FACILITY LICENSING IS A PREREQUISITE TO PRODUCT REGISTRATION**

# PRE- PACKAGED FOOD PRODUCT REGISTRATION REQUIREMENT (Imported & Local)



Local

- |                         |     |             |
|-------------------------|-----|-------------|
| Cottage Industry        | -   | GH¢ 300.00  |
| •Small Scale Industry   | -   | GH¢ 600.00  |
| •Medium Scale Industry- | GH¢ | 900.00      |
| •Large Scale Industry   | -   | GH¢ 1500.00 |



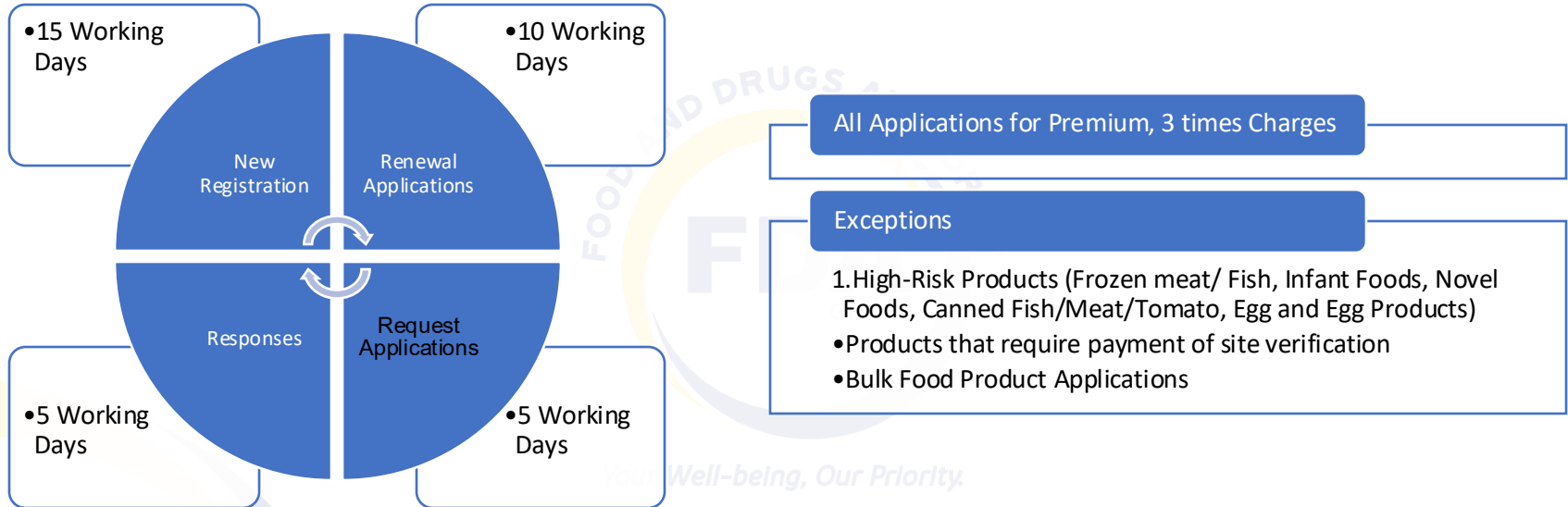
Imported

- |                          |   |            |
|--------------------------|---|------------|
| 1 to 30 Products         | - | GH¢ 750.00 |
| •31 to 500 products      | - | GH¢ 600.00 |
| •501 to 1000 products    | - | GH¢ 450.00 |
| •More than 1000 products | - | GH¢ 300.00 |



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# PREMIUM SERVICES TIMELINES FOR FOOD REGISTRATION





# FOOD SERVICE ESTABLISHMENTS



Cover Letter



Completed  
Application Forms



Copy of Business  
Registration  
Certificate



Copy of Food  
Handlers  
Certificates for  
Cooks and Waiters



Application Fee:

Small Industry

-GH¢120

Medium Industry

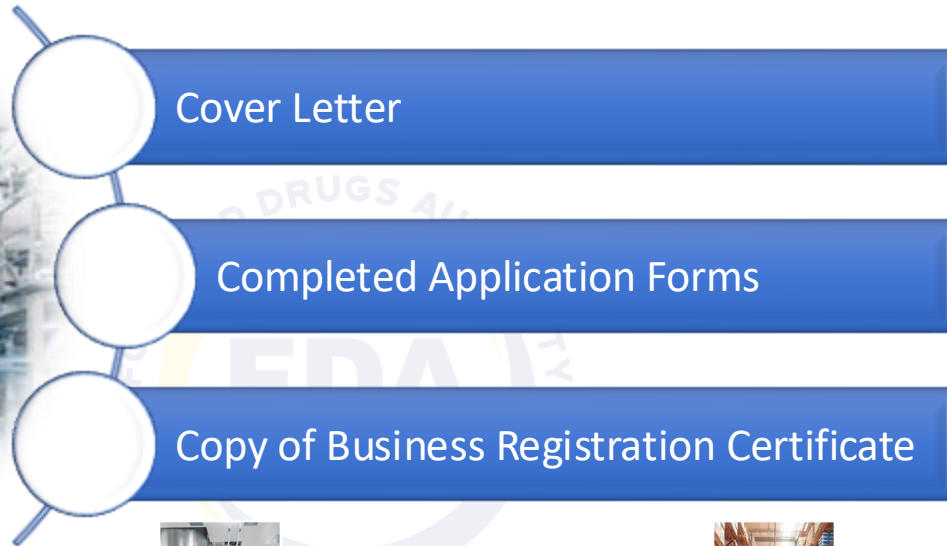
-GH¢240

Large Industry

-GH¢600



# STORAGE AND MANUFACTURING FACILITIES - DRUGS



Cottage	-GH¢ 200 per year
Small Scale	-GH¢ 300 per year
Medium Scale	-GH¢ 400 per year
Large Scale	-GH¢ 500 per year



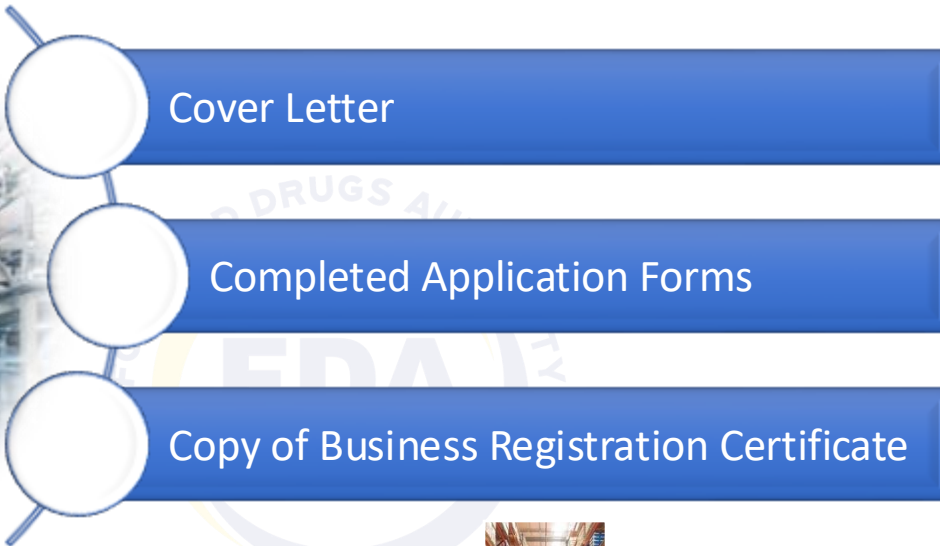
Pharmaceutical

Small Scale	-GH¢ 1000
per year	
Large Scale	-GH¢ 3000
per year	

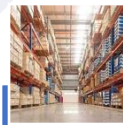


Cottage	-GH¢120
Small Scale	-GH¢240
Medium Scale	-GH¢500
Large Scale	-GH¢800

# STORAGE AND MANUFACTURING FACILITIES – COSMETICS/ MDCHC



Cottage	-GH¢ 50 per year
Small Scale	-GH¢ 100 per year
Medium Scale	-GH¢ 200 per year
Large Scale	-GH¢ 400 per year



Cottage	-GH¢120
Small Scale	-GH¢240
Medium Scale	-GH¢500
Large Scale	-GH¢800

# SITE VERIFICATIONS – OTHER THAN FOOD



\$10,500.00 when importing  
from outside Africa



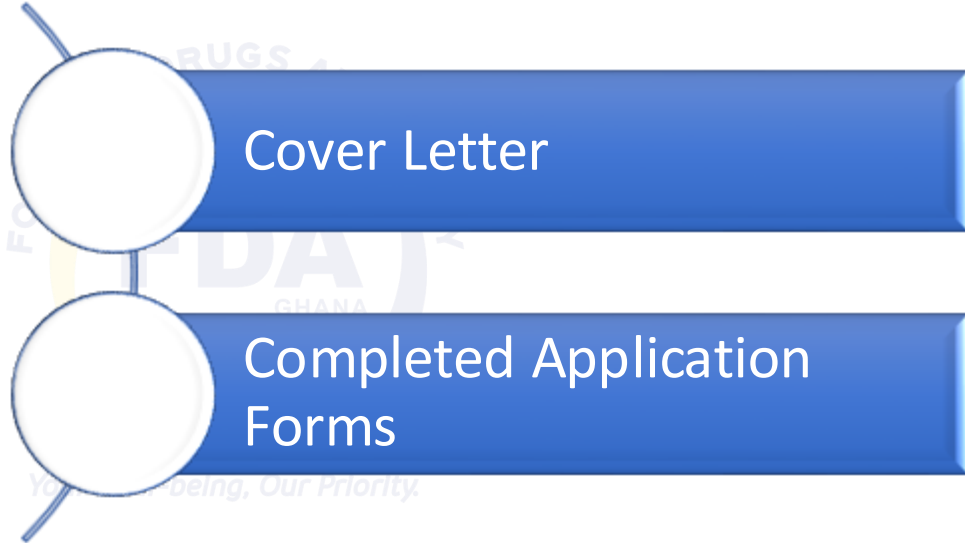
\$8,000.00 when importing  
from Africa



\$6,000.00 when importing  
from West Africa

NB: FACILITY LICENSING IS A PREREQUISITE TO PRODUCT REGISTRATION

# IMPORT PERMIT



# Registration Requirements for Drugs

- Cover Letter
- Completed Dossier on 2 CD's
- Samples - Sample Schedule
- Fee:
  - Imported - \$1,200
  - New Chemical - \$1800
  - Orphan Drugs - \$300
- Local – GHC5,000
- Veterinary - \$ 600

Allopathic



- Cover Letter
- Completed Application Forms
- Certificate of Analysis
- Stability Study Report\*
- Free Sale Certificate\*
- Samples
- Fee:
  - Imported - \$1,200
  - Local – GHC500

Herbal



- Cover Letter
- Completed Application Forms
- Certificate of Analysis
- Stability Study Reports\*
- Free Sale Certificate\*
- Samples
- Fee
  - Imported - \$ 600
  - Local – GHC500
  - Veterinary - \$600

Supplements



- Cover Letter
- Completed Dossier on 2 CD's
- Samples
- Fee:
  - Imported - \$1800
  - Local – GHC 2,500

Biologics



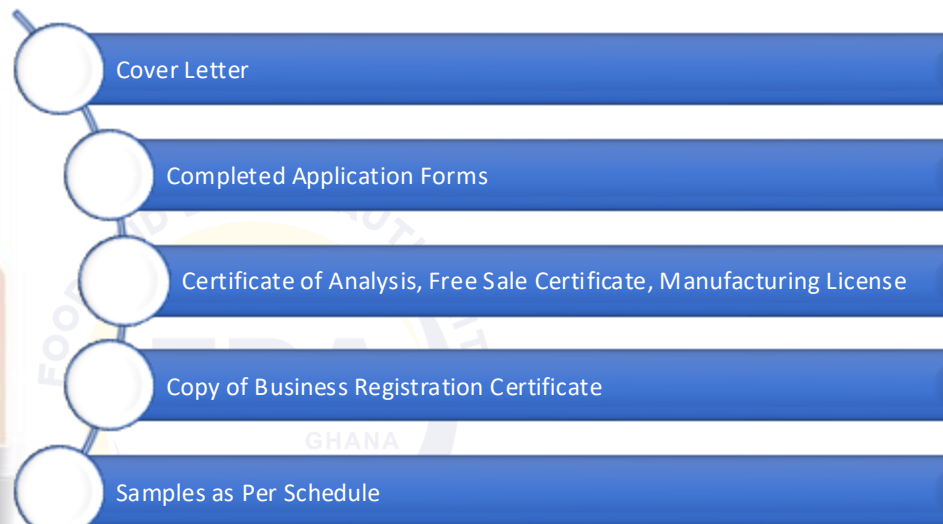
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# COSMETICS, HOUSEHOLD CHEMICALS



Local

Cottage Industry	-GH¢ 300
Small Scale Industry	-GH¢ 600
Medium Scale Industry	-GH¢ 900
Large Scale Industry	-GH¢ 1,500



Imported

1-30 Products	-\$177
31-500 Products	-\$111
501-1000 Products	-\$72
> 1000 Products	-\$21



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# MEDICAL DEVICES REQUIREMENTS



Cover Letter

Completed Application Forms

Certificate of Analysis, Free Sale Certificate, Manufacturing License

Copy of Business Registration Certificate

Samples as Per Schedule



Local

Class I : GHC750  
Class II: GHC900  
Class III: GHC1,050  
Class IV: GHC1,200



Imported

Class I : \$180.  
Class II: \$300.  
Class III: \$480.  
Class IV: \$600.



# ADVERTISEMENTS



Cover Letter



Completed Application Forms



Advert Script/ Artwork/ Storyboard



Copy of Product Registration Certificate



Application Fee: Per  
Media/language/Script/Product

Regular  
Express

-GH¢800  
-GH¢2,000



# THANK YOU

ANY QUESTIONS  
PLEASE?



[www.fdaghana.gov.gh](http://www.fdaghana.gov.gh)