 <small>Your Well-being, Our Priority.</small>	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/TTP/FOR – 08	
		Page 1 of 13	Ver. No.: 01
		Effective Date: 26/02/2025	
TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT			


APPLICATION FORM  
FOR THE REGISTRATION OF TOBACCO  
PRODUCT

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APPLICANTS  
DOUBLE  
CHECKLIST

FDA  
CHECKLIST

<input type="checkbox"/>	Signed Declaration	<input type="checkbox"/>
<input type="checkbox"/>	Covering Letter	<input type="checkbox"/>
<input type="checkbox"/>	Completed Application Form	<input type="checkbox"/>
<input type="checkbox"/>	Certificate of Analysis of Finished Product	<input type="checkbox"/>
<input type="checkbox"/>	Manufacturing License	<input type="checkbox"/>
<input type="checkbox"/>	Samples	<input type="checkbox"/>

 <p><b>FOOD AND DRUGS AUTHORITY</b></p>	<p><b>FOOD AND DRUGS AUTHORITY</b></p>		<b>DOC. TYPE: FORM</b>	
			<b>DOC NO.: FDA/TTP/FOR – 08</b>	
			<b>Page 2 of 13</b>	<b>Ver. No.: 01</b>
			<b>Effective Date: 26/02/2025</b>	
<p><b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b></p>				

\*any relevant documentation or reference material which will aid in the registration process should be attached

(To be submitted in duplicate)

#### A. COVER LETTER

Addressed to:

THE CHIEF EXECUTIVE OFFICER  
 FOOD AND DRUGS AUTHORITY  
 P.O.BOX CT 2783  
 CANTONMENTS-ACCRA GHANA.  
 +233-302-233200/235100 fda@fda.gov.gh

Samples and printed material should accompany completed forms

#### B. PRODUCT INFORMATION


Type of Product:.....

Name of Product:.....

Brand Name:.....

Net Weight/Number of Sticks per pack .....

Country of Shipment:.....Country of Origin.....

 <small>Your Well-being, Our Priority.</small>	<b>FOOD AND DRUGS AUTHORITY</b>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		Page 3 of 13	Ver. No.: 01
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

### C. DETAILS OF APPLICANT

Name of Applicant:.....

Company

Address:.....

.....

Tel. No:.....Fax:.....

E. mail:.....

### D. DETAILS OF MANUFACTURER

Name of Manufacturer:.....

Manufacturing site/ Location Address:.....

.....

.....

Postal Address:.....

.....


Tel. No:.....Fax:.....E. mail.....

### E. DETAILS OF LOCAL AGENT

Name of

Company:.....

Company

 Your Well-being, Our Priority.	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/TTP/FOR – 08	
		Page 4 of 13	Ver. No.: 01
		Effective Date: 26/02/2025	
TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT			

Address:.....  
.....

Tel.No:.....Fax:.....

E. mail:.....

Contact Person:.....

Tel. No:.....

#### F. DECLARATION

I/We the undersigned, hereby declare that all information contained herein and in the appendices is correct and true.


Name:.....

Position in company:.....

Date:..... Signature:.....

Official Stamp:.....

(Declaration should be signed, stamped and dated by the applicant)

 <p><b>FOOD AND DRUGS AUTHORITY</b></p>	<b>DOC. TYPE: FORM</b>	
	<b>DOC NO.: FDA/TTP/FOR – 08</b>	
	Page <b>5</b> of 13	Ver. No.: <b>01</b>
	<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>		

Attach a copy of a complete Tobacco Product dossier for the manufacture of this tobacco product.

The following information should be provided in the dossier:

## APPENDIX I GENERAL PRODUCT SPECIFICATIONS


Name of  
Product:.....

Brand  
Name:.....

Net Weight/Number of Sticks per  
pack:.....

The following is an example of a table for Information required on:

- (a) Active ingredients, giving the common names, chemical names, commercial name, biological origin, specifications and amount (mg/g and mg/unit)
- (b) All other ingredients giving specifications, quantities and reasons for inclusion e.g., preservative, antioxidant etc:
- (c) Additional raw materials (if any) used in the manufacturing process and not in the final product.

	<b>FOOD AND DRUGS AUTHORITY</b>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		<b>Page 6 of 13</b>	<b>Ver. No.: 01</b>
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

Ingre- #	dient Common name	Commercial Name	Chemical Name	Biological Origin	Reason for inclusion of ingredient	CAS No.	Amt (mg/g )	Amt (mg/unit)

d. For cigarettes, cigarette tobacco, leaf tobacco, pipe tobacco, cigars, kreteks, bidis and smokeless tobacco:


- information on more than 20 constituents of whole/ unburned tobacco (Refer to index 1)
- information on product packaging; and
- information on research projects undertaken by or on behalf of a manufacturer; applicable studies include those that examine the toxicity and health effects of tobacco products, their taste and flavour, the modification and development of tobacco products, and the ingredients in tobacco products

e. For cigarettes, cigarette tobacco, leaf tobacco, and

kreteks only:

- information on more than 40 toxic emissions in both mainstream and side-stream smoke (refer to index 2)

NOTE: Reference to the following publications will, where applicable be accepted

 <small>Your Well-being, Our Priority.</small>	<b>FOOD AND DRUGS AUTHORITY</b>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		Page 7 of 13	Ver. No.: 01
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

- International Organisation for Standardisation (ISO) Standards for Tobacco and Tobacco Product(s)
- Such other works of reference as may be approved by the Authority from time to time.

## APPENDIX II Manufacturing Procedures and related controls

Name of  
Product:.....

Brand  
Name:.....

Net Weight/Number of Sticks per  
pack:.....

- a. Give a brief summary of the manufacturing procedure

.....

.....

- b. (i) Name and address of manufacturer and certificate(s) of analysis of raw materials used:

.....

.....

- (ii) Certificate (s) of In-house Quality Control Tests performed on raw materials:

.....

.....

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 <small>Your Well-being, Our Priority.</small>	<b>FOOD AND DRUGS AUTHORITY</b>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		<b>Page 8 of 13</b>	<b>Ver. No.: 01</b>
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

c. Attach the final analytical report and authorization for release and any other appropriate records

.....  
.....

d. Attach certificate of Analysis (COA) for finished product (see index 3 for requirements of COA) and this should not be more than six (6) months at the time of submission

.....  
.....

e. Attach names, address, qualification of Authorized person(s) in charge of production, quality control, packaging and release of product

.....  
.....

f. Proposed shelf life of product(s)

.....  
.....  
.....

g. Stability data and justification on which shelf life has been predicted

.....  
.....

**APPENDIX III Administrative Status of the Product**

Name of



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 <small>Your Well-being, Our Priority.</small>	<b>FOOD AND DRUGS AUTHORITY</b>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		<b>Page 9 of 13</b>	<b>Ver. No.: 01</b>
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

Product.....

Brand

Name:.....

Net Weight/Number of Sticks per pack:.....

1 (a) Has an application for the registration of the tobacco product(s) been made in any other country? YES/NO\*

If YES, list countries

.....

(b) Has the product(s) been registered in any other country? YES/NO\*

If YES attach copies of certificates of registration in respect of such product(s) issued by the appropriate authority established for the registration of tobacco products in the country.

.....

.....

(c) Has the registration of the tobacco product(s) been rejected, refused, deferred or cancelled in any country? YES/NO\*


If YES, state details

.....

2. Is the tobacco product(s) manufactured in other countries? YES/NO\*

If YES, state details and list manufacturing plants from which imports can be made to Ghana.

.....

 <small>Your Well-being, Our Priority.</small>	<b>FOOD AND DRUGS AUTHORITY</b>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		Page 10 of 13	Ver. No.: 01
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

\*Tick (✓) where applicable

**APPENDIX IV**  
List of Attached documents and material

Name of  
 Product:.....

Brand  
 Name:.....

Net Weight/Number of Sticks per pack:.....

a. Attach six (6) copies of labels and packaging materials (with 3 pairs of pictorial health warning) proposed for marketing in this country

.....

.....

\* The text of labels and written material should conform to Food and Drugs Authority (FDA) guidelines for labelling of tobacco products

**APPENDIX V**


**SAMPLE SCHEDULE FOR REGISTRATION AND RE-REGISTRATION OF PRODUCTS**

**ALL PRODUCTS SHOULD BE IN A FINAL PACKAGE READY FOR THE MARKET AND SHOULD NOT BE MORE THAN SIX MONTHS AT THE TIME OF SUBMISSION.**

**THE FDA MAY REQUEST FOR MORE SAMPLES AS MAY BE DEEMED NECESSARY.**

PACK SIZE

QTY

 <p><b>FOOD AND DRUGS AUTHORITY</b></p> <p><small>Your Well-being, Our Priority.</small></p>	<p><b>FOOD AND DRUGS AUTHORITY</b></p>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		Page 11 of 13	Ver. No.: 01
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

(a) Bidis, cigarettes, kreteks

Carton (1 pack x 10)	1
----------------------	---

(b) Cigarette tobacco and pipe tobacco;

Pouch	6
-------	---

Can	6
-----	---

(c) Cigars,

Tube	10
------	----

Flip-top box	4
--------------	---

Soft package	4
--------------	---

Bundle	4
--------	---

(d) Chewing tobacco and snuff,

Plastic container	6
-------------------	---

Metal container	6
-----------------	---


## INDEX 1

Constituents (unburned tobacco): Nicotine, Nornicotine, Anabasine, Anatabine, Ammonia, Propylene glycol, Triethylene glycol, Nickel, Lead, Chromium, Arsenic, Selenium, Mercury, Benzo[a]pyrene, Nitrate, N-nitrosornicotine, 4-(Nnitrosomethylamino)-1-(3-pyridyl)-1-butanone, N-nitrosoanatabine, N-nitrosoanabasine, Triacetin, Sodium propionate, Sorbic acid, and

Eugenol [2-Methoxy-4-(2-propenyl)-phenol]

## INDEX 2

a. Emissions from mainstream smoke:

 <p><b>FOOD AND DRUGS AUTHORITY</b></p> <p><small>Your Well-being, Our Priority.</small></p>	<p><b>FOOD AND DRUGS AUTHORITY</b></p>	<b>DOC. TYPE: FORM</b>	
		<b>DOC NO.: FDA/TTP/FOR – 08</b>	
		<b>Page 12 of 13</b>	<b>Ver. No.: 01</b>
		<b>Effective Date: 26/02/2025</b>	
<b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b>			

Ammonia, 1-aminonaphthalene, 2-aminonaphthalene, 3-aminobiphenyl, 4aminobiphenyl, Benzo[a]pyrene, Formaldehyde, Acetaldehyde, Acetone, Acrolein, Propionaldehyde, Crotonaldehyde, Butyraldehyde, Eugenol [2-Methoxy-4-(2-propenyl)phenol], Hydrogen cyanide, Mercury, Lead, Cadmium, NO, Nox, N-nitrosornicotine,

4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone, N-nitrosoanatabine, Nnitrosoanabasine, Pyridine, Quinoline, Styrene, Hydroquinone, Resorcinol, Cathecol, Phenol, m+p-Cresol, o-Cresol, Tar, Nicotine, Carbon Monoxide, 1,3-Butadiene, Isoprene, Acrylonitrile, Benzene and Toluene


b. Emissions from sidestream smoke:

Same as (a) above, excluding Eugenol

### INDEX 3

### PARAMETERS FOR CERTIFICATE OF ANALYSIS FOR TOBACCO AND TOBACCO PRODUCTS

1. Circumference (mm)
2. Length (mm)
3. Filter length (Butt) mm
4. Density of cigarette at 13.5 % moisture content
5. Moisture content, % by mass
6. Nicotine alkaloids content (%) by mass on dry Wt basis
7. Nicotine content, mg/cig
8. Carbon monoxide, mg/cig
9. Tar content, mg/cig
10. Loose shorts (% by mass)

 <p><b>FOOD AND DRUGS AUTHORITY</b></p>	<p><b>DOC. TYPE: FORM</b></p> <p><b>DOC NO.: FDA/TTP/FOR – 08</b></p> <p>Page 13 of 13      Ver. No.: 01</p> <p><b>Effective Date: 26/02/2025</b></p>	
<p><b>TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT</b></p>		

- a. Plain cigarette
- b. Filter tipped cigarette
- 11. Width of tobacco shreds    12. Metallic contaminants
- a. Lead (Pb), mg/cig
- b. Cadmium (Cd), mg/cig
- c. Arsenic (As), mg/cig
- d. Mercury (Hg), mg/cig

NOTE: Certificate of analysis of tobacco and tobacco products should include the above parameters but not be limited to these.