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Effective Date: 26/02/2025

TITLE: APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT

APPLICATION FORM FOR THE REGISTRATION OF TOBACCO PRODUCT

APPLICANTS DOUBLE	FDA
CHECKLIST	CHECKLIST
	Signed Declaration
	Covering Letter
	Completed Application Form
	Certificate of Analysis of Finished Product
	Manufacturing License
	Samples





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*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

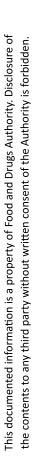
CANTONMENTS-ACCRA GHANA.

+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





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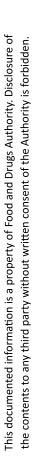
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C. DETAILS OF APPLICANT

Name of Applicant:	
Company	
Tel. No:	Fax:
D. DETAILS OF MANUFACTUR	RER
Name of Manufacturer:	
Manufacturing site/ Location Addres	ss:
Postal Address:	
Tel. No:Fax:	E. mail
E. DETAILS OF LOCAL AGEN	Γ
Name of Company:	
Company	





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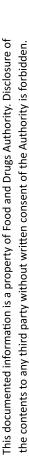
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Address:
Tel.No:Fax:
E. mail:
Contact Person:
Tel. No:
F. DECLARATION
I/We the undersigned, hereby declare that all information contained herein and in the appendices is correct and true.
N.
Name:
Position in company:
Date: Signature: Signature:
Official Stamp:
(Declaration should be signed, stamped and dated by the applicant)





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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	

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) <u>All</u> 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.



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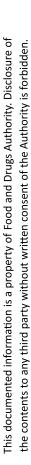
Ingre- dient					CAS	Amt	Amt
	Commercial Name			for inclusion	No.	(mg/g	(mg/unit)
#	IName	Name	O	of)	, ,
				ingredient			

- 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





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- 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





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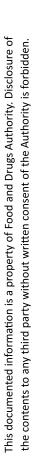
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	Attach the final analytical report and authorization for release and any other appropriate records
d.	Attach certificate of Analysis (COA) for finished product (see index 3 for requirements of COA) and this should not be more than six (6) months at the time of submission
	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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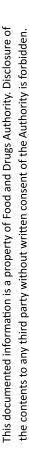
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Product
Brand Name:
Net Weight/Number of Sticks per pack:
1 (a) Has an application for the registration of the tobacco product(s) been made in any other country? YES/NO*
If YES, list countries
(b) Has the product(s) been registered in any other country? 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.





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*Tick ($\sqrt{}$) 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



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(a) Bidis, cigarettes, kreteks	
Carton (1 pack x 10)	
(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-nitrosonornicotine, 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:



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Ammonia, 1-aminonaphthalene, 2-aminonaphthalene, 3-amonobiphenyl, 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-nitrosonornicotine,

4-(N-nitrososmethylamino)-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)



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- 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.