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APPLICATION FORM FOR THE REGISTRATION OF A TOBACCO PRODUCT

TITLE: APPLICATION FORM FOR THE REGISTRATION OF A TOBACCO PRODUCT

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

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

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(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@fdaghana.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……

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……..

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E. DETAILS OF LOCAL AGENT

Name of Company:…….

Company 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)

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.

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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 sidestream smoke(refer to index 2)

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

- 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.

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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:

……
……..
……
……..
……

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

……
……..
……..
……

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(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

……
……
……

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APPENDIX III

ADMINISTRATIVE STATUS OF THE PRODUCT

Name of 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.

……

*Tick (√) where applicable

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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
(*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

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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-(N-nitrosomethylamino)-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:
Ammonia, 1-aminonaphthalene, 2-aminonaphthalene, 3-amonobiphenyl, 4-aminobiphenyl, 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, N-nitrosoanabasine, 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)
    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.

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