FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE REGISTRATION OF TOBACCO PRODUCTS

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1.0 INTRODUCTION

Tobacco is the single most preventable cause of death in the world today. Currently, about **7 million deaths** occur annually from tobacco-related diseases (cancers, heart diseases, lung disease, stroke); this could almost double **in 20 years** if prevalence of tobacco use remains constant. It is estimated that more than 80% of smokers worldwide live in low and middle-income countries where the burden of tobacco-related illness and death is heaviest.

In response to the growing threat of the tobacco epidemic, in the year 2004, 192 member states of the World Health Organisation (WHO), including Ghana, adopted the Framework Convention on Tobacco Control (FCTC). Parties to the WHO FCTC have committed to protect the health of their populace by joining the fight against the tobacco epidemic and are enjoined to take administrative, legislative and any other means to curb the incidence of smoking and reduce the hazards associated with smoking.

2.0 LEGAL BASIS

In pursuance of the Part Six (Tobacco Control Measures) of the Public Health Act, 2012 (ACT 851) and the Tobacco Control Regulations, 2016 (L.I.2247), FDA is mandated to implement, enforce and regulate tobacco and tobacco products as well as initiate the prosecution of person(s) who contravenes to the provisions in these sections.
Guidelines are hereby made to provide prospective importers of tobacco with information on the general requirements for the registration of tobacco products. These Guidelines apply to all body-corporates duly registered by the Registrar-General Department which want to import and register tobacco products into Ghana.

3.0 DEFINITION OF TERMS

In these Guidelines, unless the context otherwise states:

a) **"FDA"** means Food and Drugs Authority

b) **"Applicant"** means the product owner or licence holder. Representatives of licence holders may not hold themselves as applicants

c) **"Tobacco Products"** means products entirely or partly made of the tobacco leaf as raw material which are manufactured to be used for smoking, sucking, chewing or sniffing or handled

d) **"Applicant" and "Importer"** are used interchangeably

4.0 REQUIREMENTS

4.1 REGISTRATION AS AN IMPORTER OF A TOBACCO PRODUCT

a) An application as an importer of a tobacco product shall be made in writing to the FDA.

b) An application form, **"Application for Registration as an Importer of Tobacco Product"** shall be completed in accordance with the sequence of appendices and shall be dated, signed and stamped by the applicant/licence holder.

c) Applications shall be accompanied by:

- A duly signed covering letter
- Completed application form
- All supporting documents as specified in the application form
- Non-refundable application fee as specified in FDA's Fees Schedule

d) The FDA shall approve the application before any importation of the product shall be made into the country.

e) The registration as an importer of tobacco products shall be valid for one (1) year.

4.2 RE-REGISTRATION AS AN IMPORTER OF A TOBACCO PRODUCT

a) An application for re-registration as an importer of a tobacco product shall be made in writing to the FDA. The application shall be accompanied by:

- A duly signed covering letter
- A copy of the Certificate of Registration from the Registrar General's department
- Contact information (Postal Address, Location Address, E-mail Address, Telephone Numbers, Fax Numbers) of all Distributors
- Non-refundable application fee as specified in FDA's Fees Schedule

b) The FDA shall approve the application before any importation of the product shall be made into the country.

4.3 REGISTRATION OF A TOBACCO PRODUCT

a) An application for the registration of a tobacco product shall be made in writing to the FDA.

b) An application form, **"Application form for the Registration of a Tobacco Product"** shall be completed in accordance with the sequence of appendices and shall be dated, signed and stamped by the applicant/licence holder.

c) Applications shall be accompanied by:

- A duly signed covering letter
- Two (2) completed application forms
- All supporting documents as specified in the application form
- Non-refundable registration fee as specified in FDA's Fees Schedule

d) The Authority shall acknowledge receipt of application to the applicant within 15 working days upon receipt of the application.

e) The Authority shall process the application for registration within three months if the applicant meets the requirements for registration

f) The Authority shall issue a license to the applicant, and that license shall be valid for one year from the date of issue.

g) Where an applicant is not satisfied with the decision of the Authority the applicant may appeal to the Minister within thirty days of receipt of the decision and the Minister shall respond within fifteen days.

h) The FDA shall approve the application before any importation of the product shall be made into the country.

4.4 RE-REGISTRATION OF A TOBACCO PRODUCT

a) An application for the re-registration of a tobacco product shall be made in writing to the FDA.

b) Applications shall be accompanied by:

- A duly signed covering letter
- Certificate of Analysis of submitted samples
- Six (6) packs of samples with two (2) representing each pair of health warning.
- Non-refundable registration fee as specified in FDA's Fees Schedule

4.5 IMPORTATION OF A TOBACCO PRODUCT

a) An importer of a tobacco product shall import a tobacco product into the country **only** upon issuance of a tobacco import permit.

b) The importer shall submit an application for a tobacco import permit online on the Ghana Community Network (GCNet) electronic permit system.

c) The importer shall correctly enter the following details on the permit application:

- Name, full postal address and telephone numbers of the importing company
- Name, full postal address and telephone numbers of the exporting company
- The purpose of import
- The item details : shall include the following details

  - the full name of the tobacco product and the registration number

  - the total quantity of the tobacco product being imported to the smallest unit of use e.g number of sticks, total number of pouches etc **or** if a bulk quantity is stated (e.g number of cartons, number of sleeves etc), a description of the bulk quantity, to the smallest unit of use.

- Transport details (NB. This section which includes the Mode of transport, Mode of Transport Description, Shipment date, Carrier, Port of Arrival, Port of Departure, Customs Office and Freight Station shall be fully stated).

d) Upon receipt of the import permit application, the application shall be vetted by the FDA.

e) Based on the outcome of the vetting, the importer shall receive a reply from the FDA on the GCNet electronic permit system approving or rejecting the import permit application.

4.6 Sale of tobacco and tobacco products

a) A person shall not sell a tobacco product except in unopened packages containing a minimum of:

- 10 sticks of smoked tobacco products, or

- 30 grams of smokeless tobacco products.