|  |  |  |
| --- | --- | --- |
|  |  **FOOD AND DRUGS AUTHORITY**   | **DOC. TYPE: FORM** |
| **DOC NO.: FDA/DRI/DMS/AP-ADV** |
| **PAGE 1 OF 4** | **REV NO.: 00** |
| **EFFECTIVE DATE-02/2013** |
| **TITLE: APPLICATION FORM FOR ADVERTISEMENT OF DRUGS, COSMETICS, HOUSEHOLD CHEMICALS AND MEDICAL DEVICES** |

APPLICANTS FDA

CHECKLIST CHECKLIST

 **CHECKLIST**

Covering Letter

Signed Declaration

Fully Completed Application Form

Advert Script.

Advert CD (For electronic media)

Copy of Registration Letter or Certificate

Samples Submitted (2 Samples)

Evidence of Payment of Required Fees

Authorization Letter (where applicable)

**1. Type of product** (Tick as appropriate)

**(a)Drug** PoM P OTC Veterinary

**(b)Herbal (c) Homeopathic (d) Food Supplement**

**(e) Medical Device**   **(f) Cosmetic**

**(g) Household Chemical substance**

**2. Presentation or Dosage Forms** (Tick as appropriate).

(a)Tablets (b) Capsules (c) Caplets (d) Syrup

(e)Suspension (f) Soluble concentrates (g) Powder (h) Lotion

(i) Ointment (j) Cream (k) Aerosols (l) Liquids

(m) Other / specify: ……………………………………….

**3. Product Details**

1. Brand name ……………………………………………………………………………………
2. Generic name………………………………………………………………………………….
3. Product Registration Number………………………………………………………………..

***NB: Please attach a photocopy of the valid certificate of registration of the product.***

1. **Advert Details**

Has this advertisement been approved before? Yes No

Previous advertisement approval number if available: ……………………………..

1. **Particulars of organization applying for the advertisement**

Name……………………………………………………………………………………………… Address……………………………………………………………………………………………

Telephone…………………………………………………………………………………………

Email……………………………………………………………………………………………….

Please tick appropriately: Is this organization

The product License Holder/Product Applicant Manufacturer

 Importer / Local Distributor Third Party

***\*If 3rd party provide a letter of Authorization***

1. **Proposed media for advertisement:**

 TV Radio Billboard

Posters/Flyers Newspaper/Magazine Social Media Other (please specify)…….………………………………………………………………………..

1. **Proposed language(s) for advertisement** ……………………………………………….

1. Does this advertisement mention any of the diseases listed in Schedule 5 of the Public Health Act, 2012, Act 851?

……………………………………………………………………………………………………….

1. State any known side-effects of the drug………………………………………………….

1. Any other remarks (e.g. justification for any special claims)

………………………………………………………………………………………………………

………………………………………………………………………………………………………

NB

1. A type-written copy of the script or story sketch should be submitted with the application.
2. All approved advertisement shall include the phrase “**This advertisement has been vetted and approved by the FDA**” (Refer Advertisement Approval statement attached)

**Declaration**

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

Name:……………………………………………………………………………………………

Position:…………………………………………………………………………………………

Signature:…………………………………………………………………………………………

Date:……………………………………………………………………………………………… Official Stamp:

**ADVERTISEMENT APPROVAL STATEMENT**

|  |  |
| --- | --- |
|   |  |
| **English**  | **:** This advertisement has been vetted and approved by the FDA.  |
| **Twi (Asante)**  | : FDA ahwehwɛ saa adwadie nkratoɔ yi mu agye ato mu sɛ ɛyɛ  |
| **Fante**  |   | : Dɛm dawurbɔ yi FDA ahwehwɛ mu agye ato mu.  |
|  |   |  To be read as: [ Dɛm dawurbɔ y’ FDA ahwewɛm ‘ agy’atom’]  |
| **Nzema**  |  | : FDA ɛnlea na yelie gualilɛ nolobɔlɛ ɛhye ɛdo nu.  |
| **Ewe**  |  | : FDA dzro boblododo sia me eye woda asi ɖe dzi.  |
| **Ga**  |  | : FDA ebote nɛkɛ adafitswaa nɛɛ mli fitsofitso, ni emɔ mli akɛ  |
|   |   |  akɛtsu nii.  |
| **Dagbani**  |  | **:** Kɔhimma molo ŋɔ nyɛla FDA fukumsi duu nim ni yuli shɛli ka zaŋ  |
|  |  | bɛ nuu pa di zuɣu.  |
| **Hausa**  |  | : Hukumar FDA ta duba wannan tallan kuma ta sahala shi.  |
| **Kasem**  |  | : FDA nɛ tɔla kanto ye ba sɛ we ka maŋe.  |

**Gurene (Farefari**) : La de la FDA tigere la n bisɛ gee bo sore ti ba iŋɛ mʋʋlegɔ wa.

**NOTE:** All other languages not specified above should be translated in a similar manner.