FOOD AND DRUGS AUTHORITY

GUIDELINES FOR ADVERTISEMENT OF DRUGS, MEDICAL DEVICES, COSMETICS AND HOUSEHOLD CHEMICALS

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TABLE OF CONTENTS

1 INTRODUCTION

In pursuance of Sections 59, 113, 114 and 118 of the Public Health Act, 2012, Act 851, these Guidelines are hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for submission of application for advertisement of drugs (orthodox, herbal and homeopathic medicines), medical devices, cosmetics and household chemical substances. Advertisement of Tobacco and Tobacco products in Ghana is prohibited. Applicants are encouraged to familiarize themselves with this document and the above law before submitting an application.

2 GLOSSARY

In these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

(a) ***'Advertisement'*** includes a representation by any means for the purpose of promoting, directly or indirectly, the use, sale or disposal of a product regulated under this part.

(b) ***'Advertising'*** means the publicity of goods and description of products; this includes any form of notices in circulars, handouts, label wrappers, catalogue and price lists, newspaper, magazines and many other documents made orally or otherwise or by means of projected light, sound recording, radio, presenter mentions, television, bill boards, mobile vans, social media and writings.

(c) ***'Applicant'*** means a legal entity applying for an advertisement.

(d) ***'Authority*** 'means Food and Drugs Authority.

(e) ***'Claims'*** means any representation which states, suggests or implies that a product has particular qualities relating to its origin, properties, nature, processing, composition or any other quality. Justification in respect of any claim shall be in the light of current scientific knowledge.

(f) ***'Cosmetic'*** includes a substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.

(g) '***Drugs/Medicines'*** includes

- A substance referred to in a publication mentioned in the Fourth Schedule of the public health Act, 2012, Act 851
- A substance or mixture of substances prepared, sold or represented for use in the diagnosis, treatment , mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal, or
- restoring , correcting or modifying organic functions in man or animal, and
- nutritional supplements;

(h) ***'Household Chemical Substance'*** means a substance or mixture of substances packaged for use in a domestic or office settings

(a) a germicide,
(b) an antiseptic,
(c) a disinfectant,
(d) a pesticide,
(e) an insecticide,
(f) a rodenticide,
(g) a vermicide, or
(h) a detergent;

or any other substance or mixture of substances declared by the Minister, after consultation with the Authority, to be a chemical substance.

(i) ***'Live-Presenter-Mention (LPM) Advertisement'*** means an unapproved advertisement or an approved advertisement to which variations have been made without the approval of the Authority presented by a person in a studio or any other function.

(j) ***Medicines ;*** the definition of drugs is applicable to medicines (See above)

(k) ***'Medical Device'*** means an instrument, apparatus, implement, a medical equipment, machine, contrivance, implant, in vitro reagent or any other similar or related article, including a component, part or an accessory which is

(a) recognized in the official national formulary or pharmacopoeia or a supplement to them, or

(b) intended for use in the diagnosis of a disease or any other condition, or in the cure, mitigation, treatment or prevention of disease in humans and animals, or

(c) intended to affect the structure or a function of the body of the human being or other animal and which does not achieve any of its principal intended purposes through chemical action within the body of the human being or any other animal and which is not dependent on being metabolized for the achievement of any of its principal intended purposes.

(l) ***'Over-the-counter drugs (OTC)'*** means drugs which may be purchased without a prescription.

(m) ***'Package Labeling'*** includes the label on the immediate container plus all other printed matter, such as outer wrapper, carton or leaflet associated with the package.

(n) ***'Pharmacist Initiated Medicines'*** means drugs which can be made available to a consumer by a duly qualified and registered pharmacist.

(o) ***'Prescription Medicine'*** means drugs which can only be made available to a consumer through a written order signed by a duly qualified and registered medical practitioner, dentist or veterinary surgeon and dispensed by or under the supervision of a pharmacist.

(p) ***'Product'*** means drugs (including orthodox, herbal and homoeopathic), medical devices cosmetics and household chemical substances.

(q) ***'Rational Drug Therapy'*** means appropriate therapy, recommended or prescribed which legally may be expected to remedy or ameliorate a disordered state of physical or mental health? Drugs may be logically employed for diagnostic and prophylactic purposes to prevent or lower the incidence of illness.

(r) ***'Related Products'*** means products that are complementary products or products with different strengths, pack-sizes or are variants of the same products (different flavours).

(s) ***'Sponsor'*** means a person or organization that pays for or contributes to the costs involved in the advertisement of a product.

(t) ***'Tobacco product'*** means a product entirely or partly made of tobacco leaf as raw material which has been treated or manufactured to be smoked, sucked, chewed or sniffed or handled*;*

(u) ***'Well known personality'*** includes any person who arouses sufficient interest in society. This may include historical, political, religious, academic, cultural figures, as well as movie, music and sports figures.

2.1 Acronyms

OTC : Over-the-Counter Medicines
HCP : Healthcare Practitioner
POM : Prescription only Medicines
P : Pharmacist Initiated Medicines
FDA : Food and Drugs Authority
LPM : Live Presenter Mention

3 REQUIREMENTS

3.1 Applications

3.1.1. An application for advertisement of a product shall be made in writing by submitting a completed application form with a cover letter addressed to:
The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT 2783
Cantonments –Accra

3.1.2. The application shall be accompanied by :

(a) Evidence of registration of the product (letter or certificate)

(b) Two (2) samples of the product as registered by the FDA.

(c) Proposed script, example story sketch/story board for radio & TV and artwork for billboards. These should be legible.

(d) Audio and video if applicant so desire to facilitate the vetting process[1]

(e) Non-refundable application fee for advertisement (find information on Approved Fee Schedule on the FDA website - https://fdaghana.gov.gh/images/stories/pdfs/Quick%20links/FDA%20FEES%20SCHEDULE.pdf)

3.1.3. An applicant for advertisement should be the market authorization holder or a person authorized by the market authorization holder.

3.1.4. Advertisement application may be approved, deferred or rejected after assessment within fifteen (15) working days upon receipt of the application.

3.1.5. Advertisements considered unacceptable (deferred or rejected) by the FDA will be communicated to the applicant in writing within two (2) weeks after the decision has been made on the application.

3.1.6. Deferred applications will be considered null and void if no response is received from the applicant within twelve (12) weeks after the date of the letter.

3.1.7. An approved advertisement is valid for one (1) year from the date of approval.

3.1.8. Following approval, any alterations in the approved advertisement without prior notification and subsequent approval by the FDA shall render the advertisement null and void and shall attract sanction(s).

3.1.9. Notwithstanding 4.8 above, the FDA reserves the right to revoke approval of the advertisement as a result of new evidence concerning the product's quality, safety and efficacy or any other issues of public health and safety.

[1] Notwithstanding, an applicant may be required to make amendment to the CD to conform to the script as vetted and approved by the FDA.

3.1.10. If approval of an advertisement is revoked by the FDA during the one year period of approval, an appeal may be made by the applicant to the FDA in writing within four (4) weeks after the revocation.

3.1.11. In the event of putting up an advertisement not approved by the FDA, the marketing authorization holder/representative, sponsor, advertising agent and the media organization shall be jointly and severally liable.

3.2 General Requirements

3.2.1. No person or media shall advertise any product unless the product is registered with the Authority.

3.2.2. No person or media shall advertise any registered product that has undergone some variation that has not been approved by the Authority.

3.2.3. No person or media shall advertise any product in the print, electronic media including internet or by any means unless such advertisement has been approved by the Authority.

3.2.4. All approved advertisement shall include the phrase “This advertisement has been vetted and approved by the FDA”.

3.2.5. Live Presenter Mentions (LPM) in any form are not permitted as a form of advertisement.

3.2.6. Vetted and approved script shall be read out in the format or form in which it was approved without any variations.

3.2.7. Where an advertisement script contains more than one product, there should be clarity in the claims made for each product so as not to confuse the audience.

3.2.8. An advertisement should not directly or indirectly refer to the fact that, a product is licensed by or has the approval of the Authority.

3.2.9. An advertisement shall not contain material, which refers to recommendations by scientists or health professionals or well-known personalities or organizations, who because of their status could encourage consumption of products, to the detriment of health and safety.

3.2.10. No advertisement shall be targeted at pregnant or lactating women and persons with disease conditions specified in Fifth Schedule of the Public Health Act, 2012, Act 851.

3.2.11. An advertisement shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health practitioners. Statements or illustrations must not mislead directly or by implication.

3.2.12. No advertisement shall bring the respective industry into disrepute, undermine confidence in advertising or prejudice public confidence in the product.

3.2.13. No advertisement shall disparage any product of a competitor, either directly or by implication.

3.2.14. No advertisement shall imitate the general layout, text, slogans or visual presentation or devices of other advertisements from other companies in a way likely to mislead, deceive or confuse the consumer.

3.2.15. No advertisement shall be framed in such a manner as to exploit the superstitious belief and/or induce fear in the consumer to purchase the product. No advertisement shall contain words such as magic, miracle or mystical; exotic descriptions, such as 'super potency' or such other words as to induce the daily and continuous use of the product.

3.2.16. Advertisements for a product shall present information that is reasonably balanced between side effects and contra-indications on one hand and efficacy and safety on the other hand.

3.3 Specific Requirements for Medicines/ Drugs in General

3.3.1. Drug or medicines advertising shall reflect an overall attitude of caution in relation to drug usage, with emphasis on rational use of medicines. It shall provide sufficient and balanced information to permit assessment of risk against the benefits.

3.3.2. No advertisement for drugs shall contain any price competition or similar schemes.

3.3.3. No drug advertisement shall contain offers of gifts or refund of money to dissatisfied consumers.

3.3.4. Promotion of drugs shall not include its free distribution to the general public, except to healthcare professionals in accordance with section 121 of the Public Health Act 2012, Act 851. Records on distribution of free samples should be kept to allow traceability.

3.3.5. No drug advertisement shall state or imply in absolute terms or by quotations taken out of context, that any drug product is 'safe', 'non-toxic' or 'has guaranteed efficacy'.

3.3.6. An advertisement for drugs which contravenes the ethical standards of the health and other professions is prohibited.

3.3.7. No drug advertisement shall make statements claiming or implying superlative functions such as being the "drug of choice", 'the most frequently prescribed', 'the only drug for the purpose or that the drug has no side effects.

3.3.8. The indications for use of any therapeutic agent must conform to the approved label.

3.3.9. In advertising a drug for indications deemed acceptable by the provisions of this guideline (such as waist pains and piles), the advertisement shall neither directly, indirectly, covertly nor overtly either through the use of words or scenes, advertise the product for sexual enhancement, erectile dysfunction or any other condition connected with the human reproductive functions or disease of the reproductive organ.

3.3.10. All drug advertisement must comply with existing guideline for the treatment/management of disease conditions.

3.3.11. Tobacco and tobacco products shall not be advertised either directly or indirectly. This implies furthermore that, a person shall not:

(a) use a tobacco trademark, brand logo or brand name of a tobacco product; or

(b) advertise tobacco, a tobacco product or a tobacco related product on a billboard, wall mural, public transport, transport stop or station including an airport and sea port in any advertisement of a product, or in the organization of an activity or event.

3.4 Specific Requirements for OTC Medicines

3.4.1. No advertisement of OTC medicines (including allopathic, food supplements, herbal and homeopathic) shall:

(a) Imply that the consumer is suffering, or without treatment may suffer or suffer more severely from any illness, ailment or disease.

(b) Over-dramatize any symptoms or signs.

(c) Denigrate or attack unfairly any competitive products, goods and services.

3.4.2. OTC medicines including allopathic, food supplements, herbal and homeopathic, shall not be advertised for diseases specified in the Fifth Schedule of the Public Health Act 2012, Act 851.

3.4.3. An advertisement of an OTC medicine shall advise the consumer on any age restrictions and special precautions and the need to seek medical attention should the symptoms persist after 48 hours.

3.5 Specific Requirement for Pharmacist Initiated (P) and Prescription Only Medicines (PoM)

3.5.1. No person shall advertise any prescription and pharmacist initiated medicine in the lay press or non-medical press. The product can only be advertised via scientific / medical journals, promotional materials/ product launch and such advertisement has to be vetted and approved by the authority.

3.5.2. Prescription and pharmacist initiated medicines shall be advertised only for indications for which the drug has been registered by the Authority.

3.5.3. Advertisement for any prescription and pharmacist initiated medicine in a health professional journal or materials for health professionals should contain the following information as specified on the package labelling:

(a) Names of drug product - International non-proprietary and brand name
(b) A quantitative listing of all the ingredients (APIs and excipients)
(c) An accurate statement of the dosage and strength
(d) Daily dose
(e) Frequency of administration
(f) Preparation before use (shaking, dilution, refrigeration)
(g) Quantity of contents in metric units where applicable
(h) Route or method of administration
(i) Adequate warning (cautions, side effects, interactions, treatment of overdose, effects on pregnancy and lactation), when necessary for the protection of the user as provided in drug labeling regulations.
(j) Name and address of manufacturer or packaging company. If it is an imported medicine, the name and address of the local packing company or distributor must appear on the label in such a manner as to identify the relationship between the packing company or distributor and the manufacturer.

3.5.4. Advertisements of all medicines that may be used by pregnant women and lactating mothers shall state any known side effects of the medicine on the pregnant woman, fetus and infant.

3.5.5. All data illustrations presented in advertisements including charts, graphs and tables extracted from the literature or other sources or reproduced by artwork, must be accurate, complete and clear with the source specifically identified. Data illustrations which are misleading or ambiguous or which distort the original intended meaning or interpretation either directly or by implication will be considered a violation of these regulations.

3.5.6. Claims and quotations from the scientific literature concerning efficacy, safety, adverse reactions, use in children below the age of eighteen, use in pregnancy and lactation shall mention the scientific source(s) of information. Copies of all references cited should be provided to the FDA for verification.

3.5.7. Claims based on, or quotations that have been selected from a scientific article or series of articles and emphasize only positive features while ignoring negative findings, will not be accepted. Claims and quotations must be readily verifiable by the FDA.

3.5.8. Selected quotations should not refer to another brand of the same active ingredients from a different pharmaceutical entity unless data of accepted methodology are available to warrant cross reference between products.

3.6 Specific Requirements for Medical Devices

3.6.1. A person shall not advertise a medical device for the diagnosis, treatment or cure for diseases specified in the Fifth Schedule.

3.6.2. No advertisement for medical devices shall contain any price competition or similar schemes.

3.6.3. Notwithstanding 5.5.1 and 5.5.2 advertisement of medical devices meant for health promotion and prevention of diseases of public health concern that may not require the intervention of a health professional may be permitted. Such advertisements should therefore seek to educate the general public as such.

3.6.4. No advertisement for medical devices shall contain offers of gifts or refund of money to dissatisfied consumers.

3.6.5. Promotion of medical devices shall not include its free distribution to the general public, except to healthcare professionals in accordance with section 121 of the Public Health Act 2012, Act 851. Records on distribution of free samples should be kept to allow traceability.

3.6.6. No advertisement for medical devices shall state or imply in absolute terms or by quotations taken out of context, that any medical device is ‘safe’, ‘non-toxic’ or ‘has guaranteed performance’.

3.7 Specific Requirements for Cosmetics And Household Chemicals.

3.7.1. Claims on cosmetics and household chemical substances shall not imply actions that are normally considered therapeutic in nature.

3.7.2. For insecticide aerosols and related products, re-entry periods shall be specified as a precautionary and safety measure.

3.7.3. All approved advertisement for skin toning/ skin lightening shall include the phrase **"Does not contain hydroquinone"**.

4 SANCTIONS

4.1. The provisions in the Public Health Act 2012, Act 851 Sections 119 and 129 on suspension or cancelation of licenses, fines and imprisonment upon conviction on violations of the laws or regulation will apply including Administrative charges as per the Authority's fee schedule.

APPENDIX I
PUBLIC HEALTH ACT, 2012 ACT 851, FIFTH SCHEDULE (Section 114)

Diseases for which advertisement for treatment, prevention or cure are prohibited:

(a) Sexually Transmitted Diseases, other forms of genitourinary diseases. Acquired Immune Deficiency Syndrome (AIDS) or diseases connected with the human reproductive functions.

(b) Any of the following:-

Alcoholism	Appendicitis
Amenorrhoea	Arterio-Sclerosis (Strokes)
Asthma	Blindness
Bladder Stone	Cancer
Convulsion	Deafness
Diabetes	Diphtheria
Epilepsy or fits	Diseases of the reproductive organ
Erysipelas	Fibroid
Gallstones	Goitre
Heart Disease	Hernia or Rupture
Hypertension	Infertility
Kidney Stones	Kidney Failure
Leprosy	Leukemia
Systemic Lupus Erythematosis	Locomotortazy
Mental Disorders	Nephritis or Bright’s disease
Obesity	Paralysis
Pleurisy	Pneumonia
Poliomyelitis	Prostate Disease
Scarlet Fever	Septicaemia
Smallpox	Sexual Impotence
Tetanus or Lock-jaw	Trachoma
Tuberculosis	

APPENDIX II

TEMPLATE SCRIPT FOR RADIO

Radio Advertisement script for……

Applicant/Client		Duration	
Product Name		Title(if applicable)	
Media		Language	

Person(s)	**Voice**
Mr. A:	how are you my friend?
Mr. B:	I am doing great and you?
Mr. A:	Not bad at all. Where are you coming from?
Mr. B:	Just from grandma's place.
Mr. A:	Ok then see you later
Mr. C:	But that is your brother you just referred to as friend.
Mr. A:	Yes oo. That is how we describe ourselves friends.

NB:
The above template is applicable to dialogues. Monologues scripts can be written with or without indicating the person speaking.

APPENDIX III

TEMPLATE SCRIPT FOR TV

TV Advertisement script for……

Applicant/Client		Duration	
Product Name		Title(if applicable)	
Media		Language	

VIDEO(Text or Image)		AUDIO (Voice)
scene1	Text Camera pans on Kofi as he takes couple of squatting with dumbbells Image  (collage of all worried mums and babies)	Eish, I have hurt myself Announcer: When babies have teething discomfort or minor tummy upset; they either cry, cream or frown at you
Scene 2		
Scene 3		

Etc