الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Regulations and procedures for approving advertisements for non-prescription medications

version No. 5

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Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

(Regulations and procedures for approving advertisements for non- prescription medications ~~products~~)

Drug sector

Saudi Food & Drug Authority

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comments and suggestions

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Drug sector

Saudi Food & Drug Authority

Vision and Mission

Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

Mission

Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of products, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

Documentation:

version	Date	publisher	comments
4	26\3\2017	licensing Management Executive	Updated version

Note: the updated Parts in this version are listed on the last page.

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1. Objective:

The instructions and information in this guide apply to the following:

- Non-prescription human pharmaceutical preparations.
- Herbal and health preparations.
- Non-prescription veterinary preparations

All information provided will be reviewed to ensure that the necessary documents are completed.

2.General Provisions:

1. shall not be permissible to apply for approval for advertisement except for non-prescription medications.

2. Shall not be permissible to advertise a product until after it has been registered or listed in The Saudi Food and Drug Authority.

3. The Applicant is obligated to specify the target group for the advertisement in the approval application form for an advertisement published on the Authority's website.

4. The Applicant is obligated to specify the media to be advertised in the application form, the single advertisement format may be used in a maximum of three advertising media.

5. The Applicant shall be bound by the authority demands in terms of adding, deleting or amending the commercial or advertisement.in a clear and readable font.

6. The producing company may authorize an Advertisement company to present and apply their advertisement. In this event, the following conditions must be met:

    - An authorization from the advertiser to authorize the applicant for advertising certified by the Chamber of Commerce.

    - If the third party is an advertising company, the advertising company must be licensed by the Ministry of culture and the Ministry of media.
    - Comply with any other requirements specified by the Saudi Food and Drug Authority.

7. The fee for advertising is not refunded, regardless of approval or not.

8. If a letter (request for amendments) is issued by the authority, the applicant must complete the amendments within 90 days from the date of the letter.

9. The applicant is obligated to place the Authority's approval serial decision number on the commercial or advertisement.

10. The validity of the approval for advertising is only one Hijri year.

11. Shall not be permissible to make any change or amendment to the materials or design of the approved advertisement without informing to the Saudi Food and Drug Authority, and violating this leads to the Approval Cancellation and the infliction of the necessary punishment.

12. The applicant has the right to object to the committee's decision within a maximum period of 60 days from the date of the decision.

13. The advertiser is obligated to stop advertising whenever the authority requests.

3. Regulations and procedures for approving advertisements for non -prescription products:

1. The content of the advertisement/Commercial must comply with:

1. the approved Patient Information Leaflet [PIL]. OR

2. the approved Summary of Product Characteristics [SPC]. OR

3. the approved external label. OR

4. the approved external package.

2. The advertisement must contain:

- The brand name.
- the active ingredient name if it is only one active ingredient (the scientific name is directly under the brand name so it is not less than one third of the volume of the brand name).
- In the event of an audible advertisement, the following phrase shall be written: (this product has several of side effects. To know more about them, consult your doctor or pharmacist and read product leaflet.

3, The commercial or advertisement must not conflict with the Islamic law or the traditions of society.

4. The advertisement shall not outrage the public modesty.

5. The Commercial or advertisement shall not include any phrase affecting other pharmaceutical or herbal products.

6.The commercial or advertisement must not contain information that leads to deceiving the consumer or giving misleading information.

7. The commercial or advertisement must not contain expressions that lead to unacceptable interpretation.

8. Educational phrases should be added to the advertisement, such as:

- (This product does not substitute for natural sources of vitamins) when advertising vitamins.
- (nutritional supplements are not a substitute for a balanced diet and a healthy lifestyle) when advertising nutritional supplements.
- (if symptoms persist for more than 48 hours, please consult a doctor) when advertising Pain Killer products.

4. Regulations and procedures for advertisements on internet sites:

- The advertisement does not contradict the provisions of advertisements in the Saudi Food and Drug Authority that mentioned previously.
- The advertisement must be available on the website itself, and the website shall not rely on external links to deliver the advertisement.
- the site shall not send the user to other links or sites that contain additional information or other advertisements unless previously approved.
- Shall not permissible to add a health or advertising link to another site that is not approved by the authority.

- Shall not provide Health practitioners private information to public websites.

5. Procedures for approving advertisements for non -prescription products:

Submitting the request for approval of advertisement to the Drug sector at the Saudi Food and Drug Authority, And the application shall contain the following**:**

1. Fill out the application form for approval of advertisement for non-prescription medications published on the Authority's website on the forms page.
2. Fill out the written pledge form for the approval request of advertisement for non- non-prescription medications published on the authority's website and stamp it by the applicant agency.
3. Present the commercial or advertisement content in the format in which it will be advertised.

4. A copy of the Patient Information Leaflet (PIL), a summary of the properties of the product (approved SPC), the outer label or the outer package.
5. Attach a sample of the product.
6. Pay the fees in the system of issuing payment of the monetary fees for the medicine sector services, and attach a copy of the payment invoice.
7. Attach all documents and requirements outlined in the requirements checklist.

6. Annexes:

1. A form for requesting approval for advertisements for non - prescription medications.
2. A written pledge for approval request for advertisements for non - prescription medications.
3. Requirements checklist.

1. Application approval request for advertisements for non-prescription medications:

Product information	
The scientific name:	
Brand Name:	
Pharmaceutical form:	
Category:	☐ **OTC** ☐ **herbal** ☐ ~~**medical**~~ **healthy**
Date of registration of the product:	
Manufacturer / Marketer Name:	
Product representative:	
Advertisement	
The nature of the commercial or advertisement (no more than three options can be specified)	☐ Read ☐ Audible ☐ Visual ☐ Mobile messages ☐ Internet ☐ Billboards Others. ..... :
Advertised Media *: (It is not possible to specify more than three midia)	
Target group:	☐ female ☐ male ☐ **Kid**
Duration of advertisement:	
The executing agency:	
Classification of demand	
Classification of ~~demand~~	☐ New request ☐ Renewal of the request ☐ Modify the ad wording ☐ **Other……..**
If it was previously announced, how many of the previous ads are: ..... The number of the Approval request of the advertisement:……...	
The advertisement	☐ Local product. ☐ Dubbed. ☐ Translated
the applicant information	
Authorized person name	
the employer	
Role	☐ **the director of the scientific office**

	☐ **the director of regulatory affairs**
Phone number	
Email	

I Approve that the data included in this application and the attachments are correct and actual, and that there are no restrictions or cases under consideration by the courts or official authorities against a person, institution or preparations related to the advertisement.

The official stamp — The person in charge

Applicant — Signature

2. Pledge form to request an approval for advertisements for non -prescription medications:

Dear, the Executive Vice President of the Drug sector.

may God’s peace, mercy, and blessings be upon you.

With reference to the attached application that includes the request for approval of the advertisement:

Commercial Product Name:

production Company:

Marketing Company:

Accordingly, we pledge the following:

- Not to use advertising after the stated period, which is a Hijri year from the final approval date.
- Not to add or delete any information after obtaining the final approval.
- Record the Authority’s approval decision number of the advertisement.
- Adherence to the provisions of the establishments and Drug products regulations, the system of the Food and Drug Authority and its implementing regulations.
- Provide the Authority with a copy of the advertisement before publishing.
- Shall Not claiming a refund of the fee after submitting the application.

The official stamp	The person in charge
Applicant	Signature

3. Requirements checklist.

Document	attached	Not attached	Notes
1. Cover letter			
2. Voucher for payment of the fee			
3. Application form			
4. written pledge for approval request			
5. Name, signature and title of the person in charge			
6. the stamp			
7. A hard disk (CD) for advertising format			
8. Product Sample			
9. Patient information leaflet or summary of product characteristics (if any).			
10. Authorization of the producer to the advertising party (the second party) (if any).			

- **What changes have been made to the guideline (version 5)?**

Address	Modification type
1- Objectives	new addition
2- General Provisions	Adjustments
3- Controls and provisions for advertising on internet sites.	new addition