

Translation

NOTIFICATION OF THE FOOD AND DRUG ADMINISTRATION
RE: RULES, PROCEDURES AND CONDITIONS FOR THE APPLICATION AND ISSUANCE
OF A LICENSE TO ADVERTISE HERBAL PRODUCT,
B.E. 2564 (2021)*

By virtue of the provisions of section 70 paragraph two and section 73 paragraph two of the Herbal Products Act, B.E. 2562 (2019), the Secretary-General of the Food and Drug Administration hereby issues the Notification as follows:

Clause 1. This Notification shall come into force after the expiration of ninety days from the date of its publication in the Government Gazette.

Clause 2. In this Notification:

“advertising media” means the following channels or items used as a media for advertising:

- (1) periodic print media, such as newspaper, magazine, journal, pamphlet, and non-periodic print media, such as brochure, leaflet, poster, and decal;
- (2) radio broadcasting, TV radio, movie, and video;
- (3) outdoor media, such as advertising board, digital light board, and moving media, such as advertising board attached to a vehicle;
- (4) digital media, such as internet and other online media;
- (5) other media intended for advertising purpose.

Clause 3. The following persons may apply for a license to advertise herbal product under this Notification:

* Published in the Government Gazette, Vol. 138, Special Issue, Part 144d, page 27, dated 30th June B.E. 2564 (2021)

Disclaimer: This translation is provided by the Food and Drug Administration as the competent authority for information purposes only. Whilst the Food and Drug Administration has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.

(1) a holder of certificate of formula registration, detail notification receipt, or documentation receipt of a herbal product;

(2) a licensed producer or importer of a herbal product, with the consent of the holder of certificate of formula registration, detail notification receipt, or documentation receipt of the herbal product;

(3) a person having the consent of the holder of certificate of formula registration, detail notification receipt, or documentation receipt of the herbal product, and the licensed producer or importer of the herbal product.

Clause 4. Any person who wishes to apply for a license to advertise herbal product under section 70 shall submit an application for a license to advertise herbal product (Form AHP.1) annexed to this Notification to the licensing authority, together with the following documents or evidence:

(1) advertising words prepared for each type of media;

(2) national ID number, in the case where the applicant is a natural person;

(3) name and juristic person registration number, in the case where the applicant is a juristic person;

(4) copy of power of attorney and copy of the grantor's and the grantee's national ID cards (where a power of attorney is granted);

(5) letter of consent and accompanying evidence (where the applicant is not the holder of certificate of formula registration, detail notification receipt, or documentation receipt of the herbal product);

(6) license number of the previous license to advertise (if any);

(7) academic document (if any);

(8) other document (if any), such as certification letter of a translation, certification letter of sale promotion, and other certification letter;

(9) consent for the licensing authority to access information under (2) and (6) for the purpose of inspection.

Clause 5. Upon receiving an application for a license to advertise herbal product, the licensing authority shall issue an application receipt to the applicant as evidence and shall examine the application, documents and evidence to determine whether they are correct and complete. If they are not correct or complete, such incorrectness or

incompleteness shall be recorded, and the applicant shall be notified to amend the application or submit correct and complete information, documents or evidence within the period specified by the licensing authority. In the case where the application for a license to advertise herbal product is not submitted through an electronic means, the licensing authority and the applicant shall also sign the record.

In the case where the applicant for a license to advertise herbal product fails to amend the application or fails to submit correct and complete information, documents or evidence within the period specified by the licensing authority, it shall be deemed that the applicant does not wish to proceed further and the licensing authority shall dispose of the matter from the system.

Clause 6. In the case where the application for a license to advertise herbal product, together with information, documents and evidence are correct and complete, and the applicant has paid for the expenses of the herbal product consideration process, the licensing authority shall complete the consideration of the application within one hundred and thirty days, and may issue a license to advertise herbal product only when there appears to be no ground to prohibit the advertising under section 74.

In the case where the licensing authority issues an order refusing to issue a license to advertise herbal product, the licensing authority shall send a written notice to inform the applicant, together with the reason thereof and the right to appeal within fifteen days as from the date the order is issued.

Clause 7. In the case where the licensing authority issues an order allowing the advertising of herbal product, the licensing authority shall send a written notice to inform the applicant, and the applicant shall proceed to pay the fee for license to advertise herbal product (Form AHP.2) within sixty days as from the date the notice is received. Once the applicant has paid the fee, the licensing authority shall issue the license within seven days as from the date the payment is received.

In the case where the applicant fails to pay the fee for license to advertise herbal product within the period under paragraph one, it shall be deemed that the applicant does not wish to receive the license and the licensing authority shall dispose of the matter from the system.

Clause 8. In the case where a holder of license to advertise herbal product wishes to vary the name, address and phone number of the license holder on the license, he or she shall submit an application for particular variation (Form AHP.3) to the licensing authority, together with information, documents or evidence pertaining to the particular on the license that is intended to be varied as specified in the application form for particular variation.

The provisions in clause 5 and clause 6 shall also apply to the consideration of the application for particular variation on the license to advertise herbal product and the granting of permission thereof *mutatis mutandis*.

In the case where the licensing authority issues an order permitting the particular variation under paragraph one, the licensing authority shall send a written notice to inform the applicant.

Clause 9. In the case where a license to advertise herbal product is lost, destroyed or fundamentally fading, the license holder shall submit an application for license replacement (Form AHP.4) to the licensing authority within fifteen days as from the date of knowledge of the loss, destruction or fundamental fading, together with information, documents or evidence as follows:

- (1) a notice of police report, in the case of loss;
- (2) the license to advertise herbal product or the license number, in the case of destruction or fundamental fading;
- (3) other information, documents or evidence as specified in the application form for license replacement.

A replacement of license to advertise herbal product will take a form of a license to advertise herbal product (Form AHP.2) with the same license number and the word “replacement” on the top, and will specify the day, month, and year of issuance of the replacement. The replacement will have the same validity period and conditions as the original license, and will be signed by the licensing authority.

The provisions in clause 5 and clause 6 shall also apply to the acceptance of the application for license replacement *mutatis mutandis*.

In the case where the application, together with information, documents and evidence under paragraph one are correct and complete, the licensing authority shall issue a license replacement.

Clause 10. For the purpose of providing conveniences in the notification under this Notification, the licensing authority may also notify the applicant for a license to advertise herbal product through an electronic means together with the notification in writing.

Clause 11. Applications and license to advertise herbal product shall be in accordance with the forms annexed to this Notification.

Clause 12. Submission of an application for a license to advertise herbal product, issuance of a license, issuance of a license replacement, and submission of an application for particular variation under this Notification shall be carried out mainly through electronic means. In the period where such actions remain unable to be carried out through electronic means, an application shall be submitted at the Food and Drug Administration, Ministry of Public Health, or at other places as prescribed by the Secretary-General and published in the Government Gazette.

Clause 13. For the interest of the public and consumer protection, the Food and Drug Administration may allow the general public to access and review information regarding permission to advertise herbal product in the database system after 90 days as from the date the permission is granted, except where the license holder requests for the publication of the advertisement before the 90 day period. In that case, information shall be accessible as from the date determined by the license holder.

In the case where there is a reasonable ground, a stakeholder or a person affected by the advertising may review information regarding the advertising of herbal product at any time.

Clause 14. All advertisements of herbal products which have been permitted under the Drugs Act, B.E. 2510 (1967) on the day before the date the Herbal Products Act, B.E. 2562 (2019) come into force and such permissions have not yet expired shall remain permissible until this Notification comes into force.

Clause 15. All licenses to advertise herbal products which have been issued under the Herbal Products Act, B.E. 2562 (2019) before the day this Notification comes into force and have not yet expired shall remain valid until their expiration dates.

Announced on the 28th day of May B.E. 2564 (2021)

Paisan Dankum

Secretary-General of the Food and Drug Administration

Application for A License to Advertise Herbal Product

Receiving no.
 Date
 Time
 Receiver
 Reviewer
 Date

Writing no.

Date

I (natural person/juristic person)

National ID number/justice person registration number

Address no. Soi/Alley Road

Sub-district District Province

Zip code Tel. Fax.

Having Mr./Mrs./Miss as an attorney-in-fact/a person submitting the application to the Food and Drug Administration, as follows:

1. Name of the herbal product

Registration/detail notification/documentation no. Previous license no. (if any)

Category: Herbal drug Herbal health product

2. Advertise to General public Practitioners

3. Advertising channel

3.1 Print media

- Newspaper Magazine Journal Pamphlet Brochure
 Leaflet Poster Leaflet Decal Other, specify

3.2 Radio broadcasting, TV radio, movie, and video (specify)

3.3 Outdoor media

- Advertising board Digital light board Moving media (specify)

3.4 Digital media (specify)

3.5 Other media intended for advertising purpose (specify)

Number of pages of accompanying documents Period of advertising (specify the time unit)

4. Accompanying documents in accordance with the checklist of documents accompanying the application for a license to advertise herbal product

5. For the interest of the public and consumer protection, I give my consent to the Food and Drug Administration to allow the general public to access and review information regarding the permission to advertise herbal product in the database system after 90 days as from the date the permission is granted, except where I, the license holder, request for the publication of the advertisement before the 90 day period. In that case, information shall be accessible as from the date determined by the license holder.

In the case where there is a reasonable ground, a stakeholder or a person affected by the advertising may review information regarding the advertising of herbal product at any time.

6. I certify that:

6.1 all of the statements provided above is true, and that I am aware of the rules and conditions pertaining to the granting of permission to advertise herbal product;

6.2 once the permission is received, I will proceed in accordance with the statements and conditions specified by the licensing authority

Sign The Applicant
(.....)

License to Advertise Herbal Product

License no.

Issued to:

.....

By

Address no. Mu Soi Road

Sub-district District Province

Tel.

Being the holder of a license to advertise herbal product, namely:

.....
.....
.....
.....
.....
.....
.....

Through the media, namely

.....

Application receipt no.

Permitted to advertise in accordance with the advertising word document annexed to this license, number of pages , under the conditions specified on the back of this license.

Given on Day Month Year

The license is valid until:

Day Month Year

Signature

Position

Licensing Authority

Conditions for the advertising permitted:

1. Words and pictures advertised must correspond to those permitted.
2. Only words and pictures which have not been crossed out and those precisely as amended are permitted.
3. Advertising is allowed only prior to a variation of particular on the license/certificate of formula registration/detail notification receipt/documentation receipt/label/package leaflet of the herbal product which renders it different from before.
4. Display of words or symbols in the permitted media must be in accordance with the Notification of the Ministry of Public Health on Rules, Procedures and Conditions in Relation to the Advertising of Herbal Products, B.E. 2564 (2021).
5. Advertising period is 3 years as from the day the permission is granted.
6. Other conditions as specified in the advertising word document (if any).
7. The licensing authority reserves the right to change or revoke this license.

Application for Variation of Particular on A License to Advertise Herbal Product

Writing no.

Day Month Year

I (natural person/juristic person)

Address no. Mu Soi/Alley

Road Sub-district District

Province Zip code Tel.

Having as the owner the attorney-in-fact

Age Address no. Mu Soi/Alley

Road Sub-district District

Province Tel.

Apply for variation of particular on a license to advertise herbal product, license no.

date of issuance: day month year expiration date: day month year

for a herbal product, namely

for the following particulars to be varied:

Name of the license holder (specify)

Address of the license holder (specify)

Telephone number of the license holder (specify)

With accompanying documents and evidence as follows (specify)

.....

(Signature) The Applicant

(.....)

Note: please insert a checkmark √ in in front of the statement you wish to select.

Food and Drug Administration, Ministry of Public Health

Day Month Year

Allow

Do not allow the variation of particular on the license, because

(Signature)

Position

Licensing Authority

Application for A License to Advertise Herbal Product Replacement

Writing no.

Day Month Year

I (natural person/juristic person)

Address no. Mu Soi/Alley

Road Sub-district District

Province Zip code Tel.

Having as the owner the attorney-in-fact

Age Address no. Mu Soi/Alley

Road Sub-district District

Province Tel.

Applying for replacement of a license to advertise herbal product, license number

date of issuance: day month year expiration date: day month year

for a herbal product, namely

due to the original license being lost destroyed damaged fundamentally fading

others (specify)

With accompanying documents and evidence as follows:

A notice of a police report for the loss of the license from the police station of the area where the license is lost or destroyed

The remaining license, in the case of destruction or fundamental fading

Other relevant document (specify)

(Signature) The Applicant

(.....)

Note: please insert a checkmark ✓ in in front of the statement you wish to select.

Food and Drug Administration, Ministry of Public Health

Day Month Year

Allow

Do not allow the issuance of a replacement, because

(Signature)

Position

Licensing Authority