

Check list of the documentation that needs to be submitted for renewing the registration of veterinary paramedical products, animal health care products and medical devices:

I. Administrative data:

1. Applicant's contact data

- name, address, telephone, e-mail, fax

2. In case of local representative (firm or person):

- Name of the contact person, address, telephone, e-mail, fax

3. Declaration about sales data (from the date of registration up to now)

4. Declaration about any reported undesirable effects or lack of efficacy

5. Risk/benefit assessment about the further use of the product

6. The proposed text for product leaflet and label(s) **in Hungarian language**, according to the Annex 13 of 128/2009 (X.6.) Decree of Ministry of Agriculture (It also has to be sent by e-mail (in word format) to the following address: hajosa@nebih.gov.hu)

7. Variations (if relevant)

8. Proof of payment

Fee of the administrative procedure has been determined on the basis of the Decree No. 63/2012. (VII. 2.) as amended by Decree 87/2013. (X. 1.) of the Minister of Rural Development on the amount of service fees payable in the proceedings initiated before the National Food Chain Safety Office and the agricultural administrative departments of the county government offices as well as the rules of the payment of the administration service fee. (Annex 1, Section 6.6.1.1.)

The bank details are the following:

Magyar Államkincstár IBAN: HU97 10032000 00289782 00000000

Swift code: HUSTHUHB

Please state the name of the product and the firm when transferring the fee.

The license of the renewed products is valid for indefinite time

Procedure fees:

- Paramedical products (new authorisation, renewal or variation): 20 000 HUF
- Animal health care products (new authorisation, renewal or variation): 10 000 HUF
- Medical devices (new authorisation, renewal or variation): 5000 HUF