+7 495 724 28 64
info@easydocs.pro

Documents for Animal Feed Additive Registration

1 An application for feed additive state registration in 2 copies.

2 Legal address of the manufacturer's organization (+ bank details) – 1 copy.

3 Names of the feed additive, including the international non-proprietary name, the scientific name in Latin, the main synonyms – 1 copy.

4 Original name of the feed additive, if it is registered as a trademark in accordance with the laws of the Russian Federation "On Trademarks, Service Marks and Names of Places of Origin" – 1 copy.

5 Composition of the feed additive, the quantity of components (indicating the quantitative content of the components that compose the feed additive, guaranteed analytical composition including the ranges of active substances; the number of viable cells expressed in CFU / g is determined for microorganisms; for enzymes, the number of units of activity is presented) – 1 copy.

6 Instructions for use of the feed additive (draft instructions for use of the feed additive are posted here) – 6 copies. (4 signed and sealed copies + 2 unsigned and unsealed copies)

7 Quality Certificate of feed additive (analysis certificate, quality pass) – 1 copy.

8 Data on the production of the feed additive – 1 copy.

9 Methods of quality control of the feed additive (a regulatory document for domestic producers: technical conditions or organization standard) – 1 copy. (for domestic feed additives it is recommended to submit 2 copies of the regulatory document with 3-4 title pages).

10 Preclinical Testing Results of the feed additive –1 copy.

11 Pharmacological and Toxicological Testing Results of the feed additive –1 copy.

12 Veterinary Testing Results of the feed additive –1 copy.

13 Quotation of the feed additive –1 copy.

14 Documents confirming the registration of the feed additive, if it is registered outside the Russian Federation – 1 copy.

15 Powers of Attorney

– A power of attorney, which is certified in accordance with the established procedure (or contract) from the product developer to the manufacturer with indication of the powers assigned – 1 copy.

– A power of attorney, which is certified by the manufacturer to the applicant with indication of the powers assigned (if the documents are submitted for registration by a non-manufacturer) – 1 copy.

– A power of attorney, which is certified by the applicant to the representative of the applicant with an indication of the powers assigned (if the documents are submitted for registration by a non-manufacturer) – 1 copy.

16 List of registration documents submitted – 2 copies.

!NOTE!:

- For feed additives containing live or inactivated strains of microorganisms, as well as for feed additives obtained by microbiological synthesis (amino acids, vitamins, etc. obtained using producer strains), passports of the strains deposited in international or national collections, indicating the taxonomic and species, basic biological properties, lack of genetic manipulation and safety shall be submitted.

- For the feed additives intended to enhance the pigmentation of poultry and fish products (dyes), a toxicological and hygienic assessment is presented on the possibility of using these feed additives to enhance the pigmentation of poultry and fish products.

Release of Documents

The registration documents are provided to the Federal Veterinary and Phytosanitary Service of Supervision of the Russian Federation (Rosselkhoznadzor) numbered, with a list, indicating the numbering of pages or the number of pages in each document.

After Rosselkhoznadzor has made the decision to conduct the examination of the feed additive, information about the accepted application is posted on the official website of Rosselkhoznadzor, after which the Applicant sends samples of the feed additive to the All-Russian State Center for Quality and Standartization of Animal Medicines and Feeds for the examination of its quality, in the quantity necessary to reproduce the stated quality control methods.

The applicant submits for analysis a laboratory sample in four replications (of one batch): for testing in terms of quality and safety indicators, microbiological control, mycological control, and GMO testing.

The sampling is carried out taking into account the requirements of a regulatory or technical document for a specific product in accordance with GOST 13496.0.

WHEREIN:

- for microbiological control, the applicant provides 1 package of the additive in a consumer container, but not less than 100 g (ml). If the mass (volume) of the consumer container exceeds the mass (volume) of a laboratory sample, it is collected by an aseptic method (excluding microbial contamination of products from the environment) into sterile containers, plastic bags, foil;
- for mycological control, the applicant provides 1 package of the additive in a consumer container, but not less than 100 g (ml). If the mass (volume) of the consumer container exceeds the mass (volume) of a laboratory sample, it is collected by an aseptic method (excluding microbial contamination of products from the environment) into sterile containers, plastic bags, foil;
- for GMO control, the applicant provides 1 package of the additive in a consumer container, but not less than 100 g (ml). If the mass (volume) of the consumer container exceeds the mass (volume) of a laboratory sample, it is taken into separate containers, plastic bags or foil.

THE LABORATORY SAMPLES IS MARKED INDICATING THE FOLLOWING INFORMATION:

- name and address of the manufacturer's organization;
- names and purpose of the additive;
- number and volume of the batch;
- production date;
- shelf life of the additive;
- dates of laboratory sampling;
- sample mass (volume);
- position and the name of a person conducting the sampling.

The samples are accompanied by the Sampling Certificate, indicating the place and time of sampling, the batch number, the timing of production and the end of storage of the feed additive.