

## Check-list of documents for the registration of health, dietary or food supplements in Ukraine

1. Name/Address of the finished product manufacturer. Letterhead with description of relations between all companies-participants, which take part in manufacturing process and documents preparation.
2. Power of Attorney. Certified by The Apostille.
3. Legal Status of Company commercial registration. Document, which contain a little overview of Company registration (Date, Country of registration and etc.). Original or notarized copy.
4. Certificates that applicable to your country: GMP, ISO, FDA, Free Sales. Original or notarized copy.
5. Product(s) composition (with specification of every component in g, mg or other unit) / specification with reference on current Ph status.
6. Patient leaflet/Instruction for use.
7. Certificate of analysis. On the company's letterhead (with the name of company-producer). Should match the samples batch numbers.
8. Technical documents to briefly outline the production process.
9. The results of microbiological, chemical, biological, toxicological tests –pre-clinical data.
10. Science articles, which can underline the meaning of basic components in product.
11. Description of the methods of quality control (which include all needed microbiological and other results).
12. Samples of finished products (This point must be discussed and checked with us before you had sent samples).
13. Mock-ups/ images of product secondary & primary package (preferably as in printed view and in jpg, pdf format).
14. Data related to the environmental risk assessment for products containing genetically modified organisms. (Declaration, statement must include information, that you product don't contain any genetically modified organisms and are not derived from specific risk materials).
15. Clinical data - scientific reports, trial protocols, scientific articles (preferable).

1. All mentioned data is mandatory. Other legal, scientific, technical data with regard to applied product could be required in process of evaluation in accordance with expert opinion;

2. Samples & materials intended for registration in Ukraine to be imported with special permission from Health Authorities.

*Attach all necessary documents to your letter and email to **info@alenpharm.com***

**See also:**

**Pharmaceuticals**

<http://www.alenpharm.com/docs/pharmaceuticals.pdf>

**Medical supplies**

[http://www.alenpharm.com/docs/medical\\_supplies.pdf](http://www.alenpharm.com/docs/medical_supplies.pdf)

**Cosmetics**

<http://www.alenpharm.com/docs/cosmetics.pdf>