

List of documents for the registration of cosmetics

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| 1. Administrative data regarding Name/Address of the finished medicinal product manufacturer. |
| 2. Power of Attorney. Certified by The Apostille. |
| 3. Legal Status of Company commercial registration. Original or notarized copy. |
| 4. Certificates that applicable to your country: FDA (mandatory for USA), Free Sales, Cosmetic GMP, ISO 9001. Original or notarized copy. |
| 5. Conformity Declaration stating that the applicant complies with Cosmetic Directive 76/768EEC (amended 7 September 2004). On the company's letterhead. Original or notarized copy. |
| 6. Conformity Declaration (Letter of Assurance) stating that the applicant does not use the Specified Risk Materials (SRM) and complies with 97/534/EEC of 30 July 1997. On the company's letterhead. Original or notarized copy. |
| 7. Certificate(s) of analysis. Should match the samples batch numbers (preferable). |
| 8. Mock-ups/ images of product secondary & primary package (preferably as in printed view and in jpg format). |
| 9. Leaflet/patient information. |
| 10. Product composition based on INCI system. On the company's letterhead. |
| 11. Product specification. On the company's letterhead. |
| 12. Certificate of raw materials (if applicable). |
| 13. The results of toxicology tests (if applicable). |
| 14. Clinical data - scientific reports, trial protocols, scientific articles, dermatological tests program (preferable). |
| 15. Samples. |

- 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

BAA

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