

GOVERNMENT LICENSES

FDA Certification

Document Checklist for Government Licenses

For FDA (Food and Drug Administration) approval/certification, applicable for food, drug, cosmetic or medical device products intended for the US market or under Indian FDA/State FDA.

Documents Required

- Business registration/incorporation proof of the manufacturer
- Product formulation/composition details
- Manufacturing site details and facility registration
- Labelling details of the product
- Test/lab analysis reports of the product
- Good Manufacturing Practice (GMP) compliance proof of the facility
- List of ingredients and safety data, as applicable
- Details of the authorised US Agent, if applying for US FDA (for manufacturers outside the US)

Note: The above list indicates commonly required documents. Additional documents may be requested by the concerned licensing authority depending on the specific case. Expert Registration confirms the exact requirement after a brief consultation.