

FOOD SUPPLEMENT REGISTRATION

Directorate of Traditional Medicines, Food Supplement & Cosmetic Evaluation

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National Agency of Drug and Food Control

ADMINISTRATION DOCUMENT

Local Food Supplement

Unlicensed Food Supplement

- Certificate of Manufacturer Licensed for TMs or Pharmaceutical or Food Industry *)
- Good Manufacturing Practice (GMP) Certificate

Licensed Food Supplement

Requirements are the same as local product and should attach:

- Certificate of Manufacturer Licensed for TMs. Pharmaceutical or Food industry of Licensor.
- Certificate of Manufacturer Licensed for TMs. Pharmaceutical or Food industry of License.
- Certificate of Free Sale (CFS) issued by government
- Good Manufacturing Practice (GMP) Certificate
- Licensed Agreement

*) Food industrial which could only produce food supplement in liquid and or bulk in liquid dosage form

Toll Manufacturing Food Supplement

Requirements are the same as local product and should attach:

- Certificate of Manufacturer Licensed for TMs or Pharmaceutical industry of Applicant
- Certificate of Manufacturer Licensed for TMs or Pharmaceutical or Food industry of Toll Manufacturing Industry
- Good Manufacturing Practice (GMP) Certificate
- Toll Manufacturing Agreement

Imported Food Supplement

- Certificate of Manufacturer Licensed for TMs or Pharmaceutical or Certificate of Importer Licensed for TMs or Pharmaceuticals Product or Food
- Importer Identity Number
- Letter of Authorization
- Certificate of Free Sale (CFS) issued by government
- Good Manufacturing Practice (GMP) certificate issued by government

TECHNICAL DOCUMENT

Local/Licensed Food Supplement

Formula

- Composition : active ingredients, additive/excipient in matrix
- Direction of use : the direction of use, dosage, warning, precaution; contraindication/recommendation and duration of administration, if any.

Quality and Technology

- Manufacturing Process : started from weighing of raw material to finished product
- Specification of formula's ingredients/raw material
- Finished product evaluation : Certificate of Analyzed Finished Product (organoleptics, physical-chemical, microbial and heavy metal contaminant)
- Method and result of stability study

Imported Food Supplement

The Requirements are the same as local product and should attach data from manufacturing in original country

And should be completed with :

- Certificate of safety test from laboratory which has appointed by NADFC: Organoleptics, physical-chemical, microbial, heavy metal, chemical drug, and psychotropic-narcotic contaminant.
- Toxicity test Data for food supplement which its safety has not known from laboratories which has appointed by NADFC or from country of origin.

LABELLING

The label should be includes :

- Word : "Food Supplement"
- Product Name
- Net Weight or net volume
- Name and address of manufacturer or importer
- Indication, direction of use and serving size/dosage
- Composition/ingredients in qualitative and quantitative
- Energy value per serving (in calories) for energy drink product
- Alcohol content for oral solution, if any
- Expiry date, production code and the registration number
- Contraindication, side effect and warning, if any
- Other information which related of safety, or quality or source of material according to provision
- Label should be mentioned in Indonesian Language