

Guidelines for Manufacturer/Importer of “Food Supplement” or “Dietary Supplement or “Health supplement” or Nutraceuticals as to what is meant by “Alternative Medicine and Health Products Dosage Forms”

In compliance of paragraph 50 of the judgment dated 26th February, 2018 passed by the Hon’ble High Court of Sindh, Karachi in Constitution Petition No. D-4387 of 2014 and other connected petitions, the Drug Regulatory Authority of Pakistan is pleased to make the following Guidelines:-

1. Definitions,-- In these Guidelines, unless there is anything repugnant in the subject or context,

(a) Alternative Medicine and Health Products Dosage Form: Alternative Medicine and Health Products Dosage Form is the physical form in which a finished product/formulated product is produced and dispensed for human or animal use. These dosage form can be administered through Oral, Topical, Rectal, Respiratory/ Inhaled, Nasal, Vaginal, Otic, and Ophthalmic routes. The subcategories of these Dosage Forms are mentioned in Schedule A (1, 2).

2. Application,-- Human and animal general food products are not covered under DRAP Act 2012 and the Alternative Medicine and Health Products (Enlistment) Rules, 2014 provided that:-

- (i) Any substance or mixture of substances or product do not attract the definition of Drug or Food Supplement Or Nutritional Supplement Or Therapeutic Goods as defined under DRAP Act 2012 and the Alternative Medicines and Health Products (Enlistment) Rules, 2014.
- (ii) It is not formulated into Alternative Medicine and Health Products Dosage Form or their subcategories as defined in these guidelines.
- (iii) It is not presented in the form or manner to believe the general public to be a drug, therapeutic good or food supplement.
- (iv) It is not presented with any label claim with health related benefits as defined under Alternative Medicine and Health Products (Enlistment) Rules 2014.
- (v) It does not fall under the definition of adulterated Alternative Medicine and Health Products as defined in the Alternative Medicine and Health Products (Enlistment) Rules, 2014.
- (vi) It does not contain ingredients falling under the definition of prohibited substances as defined under the Alternative Medicine and Health Products (Enlistment) Rules, 2014.

SCHEDULE A

(1) Subcategories of Human Alternative Medicine and Health Products Dosage Forms (Description)

- I. **Capsule.** A solid preparation with hard or soft shell, of variable shape and capacity, usually containing a single dose of active ingredient(s).
- II. **Collodion.** A liquid preparation usually containing pyroxylin and one or more active substances in a mixture of volatile solvents, usually ether and ethanol, intended for application to the skin. When allowed to dry, a flexible film is formed at the site of application.
- III. **Cream.** A viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, intended to be applied to the skin or certain mucous membranes.
- IV. **Ointment** A semi-solid preparation intended for topical use, usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, usually non aqueous.
- V. **Gels.** Gels are semisolid preparation consist of liquids gelled by means of suitable gelling agents.
- VI. **Granules.** Granules are preparations consisting of solid, dry aggregates of powder particles sufficiently resistant to withstand handling. Granules contain one or more active ingredients with or without excipients
- VII. **Gum, chewing.** A preparation containing one or more active ingredients in a gum base, to be chewed and subsequently discarded.
- VIII. **Insufflation** A powder containing one or more active ingredients usually diluted with a suitable inert powder. It is intended for introduction into the ear, nose, throat, body cavities or wounds.
- IX. **Liniment.** A liquid or semi-liquid preparation composed of or containing one or more active ingredients intended to be applied to the unbroken skin with friction.
- X. **Topical Liquid.** A liquid (or oily) preparation composed of, or containing one or more active ingredients.
- XI. **Lotion.** A liquid preparation composed of or containing one or more active ingredients usually intended to be applied to the unbroken skin without friction.

- XII. Lozenge.** A solid preparation, containing one or more active ingredients, usually in a flavored base, which is intended to dissolve or disintegrate slowly in the mouth to effect a local action.
- XIII. Medicated Soap .**A solid preparation derived from the action of a solution of alkali on fats or oils of animal or vegetable origin and containing one or more active ingredients in bar form.
- XIV. Mouth Wash** An aqueous solution of one or more natural active ingredients intended, usually after dilution with water, for use in contact with the mucous membranes of the oral cavity.
- XV. Oral Liquid** A preparation usually consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle. They are intended to be swallowed either undiluted or after dilution.
- XVI. Oral Liquid, Emulsion** A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.
- XVII. Powder for Oral Suspension.** for One or more active ingredients in a dry form to be reconstituted for use as an oral liquid.
- XVIII. Oral Liquid, Solution** a liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.
- XIX. Oral Suspension.** Are oral liquids containing one or more active ingredients suspended in a suitable vehicle. Suspended solids may slowly separate on standing but are easily redispersed.
- XX. Paints.** Paints are solutions or dispersions of one or more active ingredients. They are intended for application to the skin or, in some cases, mucous membranes.
- XXI. Pastes.** Pastes are semi-solid preparation containing large proportions of solids finely dispersed in the basis.
- XXII. Patch.** A system containing active ingredients which is affixed to the skin and is intended to produce a local or systemic effect by diffusion of the active ingredients to the skin.
- XXIII. Powder** A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.
- XXIV. Powder, dusting.** A finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.

- XXV. **Oral Powder.** Oral powders are preparations consisting of solids, loose, dry particles of varying degrees of fineness. They contain one or more active ingredients, with or without excipient.
- XXVI. **Solution** A liquid preparation containing, one or more active substances dissolved in a suitable vehicle.
- XXVII. **Spray** A liquid preparation for application after dispersion with a spraying device containing active ingredients of natural origin used for health related purpose.
- XXVIII. **Stick** A solid preparation containing active ingredients in stick form for local application.
- XXIX. **Tablet.** Tablets are solid preparations each containing a single dose of one or more active ingredients and obtained by compressing uniform volumes of particles. They are intended for oral administration. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active ingredient is liberated.
- XXX. **Aerosol.** Aerosols are preparations containing active ingredient of natural origin and dispensed in special containers under pressure.

(2) Subcategories of Animals Alternative Medicine and Health Products Dosage Forms

- I. **Oral liquid Suspension** are oral liquids containing active ingredients suspended in a suitable vehicle.
- II. **Solution.** A liquid preparation containing active substances dissolved in a suitable vehicle.
- III. **Oral Liquid.** preparation consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle.
- IV. **Oral Liquid, Emulsion** A dispersion of an oil in an aqueous medium either of which may contain dissolved solids, in which the aqueous medium or phase forms the continuous phase.
- V. **Tablet** Tablets are solid preparations containing active ingredients and obtained by compressing uniform quantity of particles.
- VI. **Capsule** A solid preparation with hard or soft shell, of variable shape and sizes containing a single dose of active ingredient(s) for oral administration.
- VII. **Granule** Granules are preparations consisting of solid, dry aggregates of powder particles sufficiently resistant to withstand handling. Granules contain one or more active ingredients with or without excipients.

- VIII. Powder** A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.
- IX. Premixes** are mixture of one or more substances such as vitamins, minerals and/or ingredients from botanical origin with suitable diluent and are intended for health related benefits and are to admixture animal feed before administration.
- X. Cream.** A viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, intended to be applied to the skin or certain mucous membranes.
- XI. Ointment** A semi-solid preparation intended for topical use, usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, usually non aqueous.
- XII. Pastes.** Pastes are semi-solid preparation containing large proportions of solids finely dispersed in the basis.
- XIII. Topical Liquid.** A liquid (or oily) preparation composed of, or containing one or more active ingredients intended for Health related purpose.
- XIV. Spray** A liquid preparation for application after dispersion with a spraying device containing active ingredients of natural origin used for health related purpose.
- XV. Patch.** A system containing active ingredients which is affixed to the skin and is intended to produce a local or systemic effect by diffusion of the active ingredients to the skin.
- XVI. Medicated block** is a compressed feed material that contains an active ingredient, such as a nutritional supplement, and is commonly packaged in a cardboard box. Ruminants typically have free access to the medicated block over several days, and variable consumption may be problematic.

NOTE:- Aforementioned dosage forms are also applicable for Ayurvadeic, Homeopathic, Siddha, Unani/Herbal and other Traditional Alternative Medicine System as mentioned in pharmacopoeias.