

Model Bills and Regulations Committee
Attachment for January 21, 2019 Meeting

Attachment B

Labeling of Mineral and Vitamin Units
Recommended edits

1. Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees

Add: (c) (8) Products labeled with a quantity statement (e.g. tablets, capsules, granules, or liquid) may state vitamin guarantees in milligrams per unit (e.g. tablets, capsules, granules, or liquids) consistent with the quantity statement and directions for use.

2. Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees

Revise (g) as follows:

~~(g) Guarantees for microorganisms shall be stated in colony forming units per gram (CFU/g) when directions are for using the product in grams, or in colony forming units per pound (CFU/lb.) when directions are for using the product in pounds. A parenthetical statement following the guarantee shall list each species in order of predominance.~~

(g) Guarantees for microorganisms shall list each genus and species in order of predominance, and shall be stated and conform to the following:

(1) Colony forming units per gram (CFU/g) or per pound (CFU/lb.) consistent with the directions for use; or

(2) CFU per unit (e.g., tablets, capsules, granules or liquids) consistent with directions for use and the quantity statement or weight equivalent (e.g., 1 fl. oz. = 28 grams) for liquid products.

3. Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees

Revise (h) as follows:

~~(h) Guarantees for enzymes shall be stated in units of enzymatic activity per unit weight or volume, consistent with label directions. The source organism for each type of enzymatic activity shall be specified, such as: Protease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram. If two or more~~

~~sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.~~

(h) Guarantees for enzymes shall be stated and conform to the following:

(1) Units of enzymatic activity per unit weight or volume consistent with the directions for use; or

(2) Enzymatic activity per unit (e.g., tablets, capsules, granules, or liquids) consistent with the directions for use and the quantity statement or weight equivalent (e.g., 1 fl. oz. = 28 grams) for liquid products.

(3) The source organism for each type of enzymatic activity shall be specified, such as: protease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.