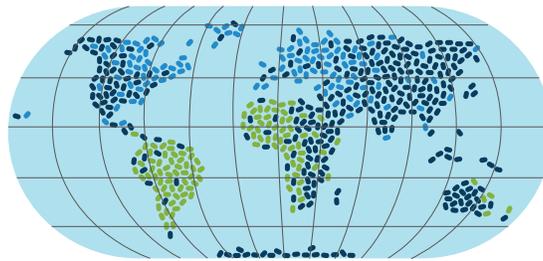




Essentials
**FOR A QUALITY
PROBIOTIC LABEL**



"The Global Voice of Probiotics®"

References

1. The Food & Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) definition of probiotics: "live microorganisms which when administered in adequate amounts confer a health benefit on the host."
2. CFU is the scientifically accepted unit of measure for probiotics. Labeling quantity in CFUs provides meaningful information to consumers about the quantity of viable microorganisms present in the product throughout shelf life. However, 21 CFR 101.36(b)(3)(ii)(A) requires that the quantity of probiotic dietary ingredients be declared in metric units.
3. When technically feasible, also declare the quantity of each genus or species in the blend.
4. 21 CFR 101.36(c)(2) requires that dietary ingredients in a proprietary blend be declared in descending order of predominance by weight.

1

Dosage

It is important to **follow dosage instructions** as directed on the probiotic¹ label.

If a **claim** pertaining to individual strains or blend of strains contained in the product is made, the manufacturer should maintain evidence that the amount provided is **consistent with the scientific evidence**.



Quantity

Colony Forming Unit (CFU)² is the scientifically accepted unit of measure for labeling the number of live probiotics in a product.

Products should declare the **total count of the blend** (single & multi-strain³) in CFUs.

You may also see milligrams (mg) for the probiotic ingredient which doesn't correspond to the activity of the formula.

2

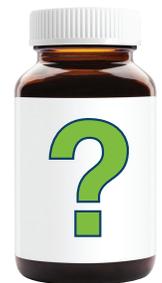
3

Strain Specificity

Probiotics have different characteristics, qualities and actions that are **unique** to the specific strain or combinations.

The label should identify the **genus, species and strain** for each microorganism in the product. i.e. *Lactobacillus acidophilus* IPA001

Individual dietary ingredients within a **proprietary blend** should be listed in descending order by CFUs⁴.



Expiration Date

The expiration date should indicate how long the probiotic product will contain the claimed levels of bacteria (CFU) when stored as directed. This is different than the date of manufacture which refers to the date the product was produced.

Products should contain **100%** of the quantity of probiotics declared on the label at end of shelf life and **not at time of manufacture**.

4

Storage

Probiotic bacteria are **living microorganisms** and their numbers can drop during storage.

It is important to read the label for proper storage instructions. Storing probiotics correctly will help ensure **viability until the expiration date**.

Probiotics are generally sensitive to changes in temperature and humidity. The **impact** is dependent on the probiotic strains, the formulation matrix, the dosage form and the packaging.



5