

QUESTIONS AND ANSWERS

FOOD

1) Does a product composed of amino acids free of phenylalanine is exempt registered at Anvisa?

Yes, food for nutrient-restricted diets are in a category that is exempt from registration by Anvisa. It must comply with all Anvisa rules (general and specific), but the regularization is through a communication to the state or municipal health surveillance service. The same one that issued the Brazilian company's basic health permit and carries out health inspection in the city or state.

2) What is the classification of the product with nutritional composition developed for a specific disease?

More information about this product is necessary to assess the Anvisa's classification, but related to disease in Brazil we have the enteral formula for specific diet therapy situation and also in specific diet therapy infant formulas for children under 3 years of age. The product will have an adequate composition for a specific disease that is presented in dossier to Anvisa. The dossier must present scientific proof of indication and nutritional adequacy for its purpose. In the labeling statements, the product may not be intended or give an indication that it is for the disease, the label should only inform its composition characteristics, among other mandatory statements for the product. The product's trademark identified its composition and is now cited by nutritionists and doctors as suitable for certain diseases, those that were thought of when the product was developed.

3) Food supplements with and without registration at Anvisa, what is the rule?

Supplements formulated with enzymes or probiotics must be registered at Anvisa. Supplements that do not contain enzymes or probiotics and that contain ingredients approved by Anvisa are regulated by a communication form to the state or municipal health surveillance service. If the company requests registration for an exempted registration supplement, the request made to Anvisa will be denied.

The ingredients (nutrients, bioactive substances, vitamins and minerals), enzymes and probiotics used in the formulation - raw material for the supplement manufacturer - must have already been approved by Anvisa to be used in the supplement. The company responsible for the ingredient is responsible for preparing a dossier on the ingredient that proves its safety and efficacy for consumption in the form of a food supplement, submitting it to Anvisa and being approved.

Regardless of registration, every food supplement must comply with all Brazilian food standards - in terms of composition, quality and labeling.

The list of approved ingredients includes: nutrient source of lycopene, source of lutein, L-carnitine, coenzyme Q10, some plant extracts, amino acids, lipids, carbohydrates, fibers, in addition to vitamins and minerals.

* For novel ingredient assessment by Anvisa, the company that request do not need to be a food company, it must be a Brazilian company with a Brazilian corporate register number - CNPJ (*Cadastro Nacional de Pessoa Jurídica*).



Some ingredients approved by Anvisa are only those produced by a company or its representative (who submitted dossier to Anvisa). The supplement manufacturer whose product is formulated with an ingredient in that condition need to be sure that it uses the ingredient that has been approved by Anvisa.

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[Ask your question, clarify your doubt.](#)

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