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CANNABIS COMPLIANCE BOARD STATE OF NEVADA

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Dietary Supplement Guidance

The Cannabis Compliance Board (CCB) issues the following guidance regarding dietary supplements for use in edible cannabis products.

Per NCCR 9.025 Requirements and restrictions on use of non-cannabis ingredients.

1. Each cannabis establishment shall ensure that it obtains non-cannabis ingredients, including hemp and CBD, for cannabis products from sources that comply with the requirements of federal and state law and regulations and are approved by the Board, including, without limitation, commercial and retail businesses.

A Dietary Supplement per the FDA "is a product intended for ingestion that, among other requirements, contains a "dietary ingredient" intended to supplement the diet. The term "dietary ingredient" includes vitamins and minerals; herbs and other botanicals; amino acids; "dietary substances" that are part of the food supply, such as enzymes and live microbials (commonly referred to as "probiotics"); and concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient from the preceding categories." (FDA Dietary Supplements - Questions and Answers.)

Dietary supplements are products intended for ingestion only and are not intended for any other route of administration. Any ingredient considered as a dietary supplement as defined by the FDA regardless of documentation provided, will not be allowed in non-edible cannabis products.

At this time any ingredients that are considered dietary supplements as defined by the FDA will not be considered for use in edible cannabis products unless the following requirements are met:

- Food processing and/or manufacturing registration certificates are supplied to the CCB showing that the 3<sup>rd</sup> party companies who are providing the ingredients that are intended to be added to the cannabis product are registered with the FDA to either manufacture and/or process food items. Registration certificate that shows 3<sup>rd</sup> party companies registered with the FDA to manufacture and/or process dietary supplements will not be accepted. (FDA Food Registration <u>Certificate</u>)
- 2. Facility must be able to provide GRAS information per ingredient in question. If the GRAS affirmation provided is solely from the source company and not on the FDA Direct Food Additives list <u>21CFR172.515</u> or the FDA GRAS list <u>21CFR182.20</u>, then the facility will need to provide the basis for GRAS determination. Basis for GRAS determination can be determined in

one of two ways, either through scientific procedures or based on common use in food prior to 1958:

- I. "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall address safety for both the target animal and for humans consuming human food derived from food-producing animals and shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods." (<u>21CFR 570.30</u>)
- II. "General recognition of safety through experience based on common use in food prior to January 1, 1958, shall address safety for both the target animal and for humans consuming human food derived from food-producing animals and may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance in the same animal species prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures." (<u>21CFR 570.30</u>)

For further guidance, please email <u>AuditInspections@ccb.nv.gov</u>.