

CRN Recommended Guidelines for Caffeine-Containing Dietary Supplements

PURPOSE:

Whether added as a pure ingredient or incorporated from a naturally-occurring source¹, caffeine is a safe dietary ingredient found in many dietary supplements. CRN supports consumer access to dietary supplements and consumers' ability to make informed decisions about caffeine in the dietary supplements they purchase. Therefore, CRN recommends that its members follow these voluntary guidelines for their products that contain caffeine, and encourages all dietary supplement producers and marketers to follow these recommendations. These guidelines address disclosure of caffeine content and set forth consumer advisories to promote the safe, responsible use of dietary supplements.

VOLUNTARY GUIDELINES:

In addition to compliance with applicable labeling laws and regulations, CRN recommends that its members adhere to the following guidelines for the labeling of caffeine-containing dietary supplements:

A. Disclosure of Total Caffeine Content

The purpose of this guideline is to provide consumers with information on the total caffeine content per serving in dietary supplements, whether from added or naturally occurring caffeine.

1. Caffeine content from both added caffeine and naturally occurring caffeine combined should be declared in milligrams per serving either in the Supplement Facts Box or in a separate statement elsewhere on the label.
2. This section does not apply to dietary supplements that contain no added caffeine and less than 25 mg per serving of naturally occurring caffeine.

B. Label Advisories for Conditions of Use

The purpose of this guideline is to provide consumers with additional information about the use of dietary supplements containing caffeine. As with all dietary supplements, consumers taking medication should consult a healthcare professional about the supplements they are taking.

1. Any supplement with total caffeine content of more than 100 mg per serving should provide the following statements or equivalent language on the product label:
 - a. This product is not intended/recommended for children and those sensitive to caffeine.
 - b. Pregnant or nursing women, those with a medical condition, and those taking medication should consult a healthcare professional before use.

C. Serving Size and Daily Intake Recommendations

¹ For purposes of this document, "added caffeine" refers to pure anhydrous caffeine. "Naturally occurring caffeine" refers to caffeine that occurs naturally in other dietary ingredients, including, but not limited to green tea, guarana, cocoa, kola nut, and yerba mate.

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The purpose of this guideline is to encourage dietary supplement manufacturers and marketers to establish caffeine levels per serving and total servings per day that are consistent with current science and in compliance with applicable laws.

1. Labeling should provide serving size and daily intake recommendations that are consistent with safety information about caffeine established by competent and reliable scientific evidence.
2. Serving size and daily intake recommendations should comply with Section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, which requires product ingredients to be safe under the conditions of use recommended in labeling, or if no conditions of use are recommended in the labeling, under ordinary conditions of use.

D. Restraints Against Marketing In Combination with Alcohol

The purpose of this guideline is to discourage marketing of caffeine-containing dietary supplements in a manner that encourages combination with alcohol.

1. CRN members should not advertise, market, or otherwise promote the use of caffeine-containing dietary supplements in combination with alcohol, or to counter the acute or immediate effects of alcohol.

E. Restraints Against the Sale and Marketing of Bulk Amounts of Pure or Highly Concentrated Caffeine in Powder or Liquid Form

The purpose of this guideline is to discourage the sale and marketing of bulk amounts of pure or highly concentrated caffeine in powder or liquid form directly to consumers.

1. CRN members should not sell or market bulk amounts of pure or highly concentrated caffeine in powder or liquid form directly to consumers.² This section is not intended to limit CRN members from marketing or selling bulk amounts of pure or highly concentrated caffeine in powder or liquid form to a business entity as part of a business transaction.

F. Implementation

1. Effective immediately, CRN recommends that dietary supplement companies comply with these guidelines.

² For purposes of this document, “bulk amounts of pure or highly concentrated caffeine in powder or liquid form” shall have the same meaning as described in the FDA guidance document *Highly Concentrated Caffeine in Dietary Supplements: Guidance for Industry* (April 2018), available at, <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM604319.pdf>

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