



Voluntary Dosage Recommendations

Council for Responsible Nutrition (CRN) Members have agreed to the following voluntary recommendations:

Vitamin A

Effective 3/87; modified 6/04

CRN recommends that labeling for all vitamin A products include a statement specifying whether retinol or carotene is the source of the vitamin A activity.

For products containing vitamin A activity from retinol:

CRN recommends that the industry adopt a maximum level not to exceed 10,000 IU (3,000 µg) per day for vitamin A supplements intended for general use by adults, and a maximum of 8,000 IU (2,400 µg) for products formulated for prenatal use.

CRN recommends that labeling for supplements containing 10,000 IU (3,000 µg) of vitamin A include direction for use indicating that it would be prudent for children, pregnant women, and women who might become pregnant, not to use more than 10,000 IU (3,000 µg) per day of supplemental vitamin A except on the advice of a physician.

For products with more than 5,000 IU (1,500 µg) and up to 10,000 IU (3,000 µg) of vitamin A as retinol or retinyl esters, CRN recommends the following labeling statement: “Not recommended for persons who regularly consumer liver.”

Vitamin D

Effective 2/09

For dietary supplement products containing vitamin D as vitamin D3 or D2:

CRN recommends that its members adopt maximum levels not to exceed 10,000 IU (250 mcg) per day for vitamin D supplements products intended for general use by adults in good health, with the exception of pregnant or lactating women. Although this amount is well above the amount specified in CRN’s ***Vitamin and Mineral Safety, 2nd Edition***, the recommendation for a maximum not to exceed 10,000 IU (250 mcg) is based on newer clinical trial data and rigorous application of the Institute of Medicine’s Tolerable Upper Intake Level (UL) risk assessment method.

The basis for this maximum is described in a peer-reviewed risk assessment by CRN staff (Hathcock and Shao) and two distinguished academic researchers with many years of experience in vitamin D. The specific reference to this publication is Hathcock et al, *Am J Clin Nutr* 2007;85:6 –18. This paper considers the additional effects from the likely high levels of vitamin D produced by some individuals with high levels of exposure to sunlight, and consumption of fortified foods.

CRN has not conducted a risk assessment with the data for vitamin D consumption by children, pregnant or lactating women, and a few diseases that may increase the likelihood of adverse effects from high intakes of vitamin D, e.g., persons with *Mycobacterium* infections, sarcoid disease, and perhaps a few others. The recommended maximum does not apply to such persons.

This recommendation applies to vitamin D2 as well as vitamin D3. The data available for the review and risk analysis that supports this policy recommendation relates mostly to vitamin D3, not to vitamin D2. CRN is not aware of sufficient data to support a risk assessment for vitamin D2. The small amount of relevant data for direct comparison of vitamins D2 and D3 suggest either that the two are equivalent, or the vitamin D2 is less potent than vitamin D3.

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Vitamin B₆

Effective 7/86; revised 6/04

CRN recommends a maximum dosage level not to exceed 100 mg per day. This level is the same as the Tolerable Upper Intake Level (UL) established by the Institute of Medicine, but is derived in a somewhat different manner.

DHEA

Effective 12/97; revised 3/09

If a member company decides to market DHEA or its precursor, pregnenolone, CRN recommends that the product comply with the following guidelines:

1. Labeled recommended daily dosage is within the range reflecting current scientific recommendations (5-75 mg);
2. The product label includes appropriate information about:
 - a) The need for consultation with a physician
 - b) The product is not intended for use for persons under 18 years of age

DHEA Marketing Guidelines Adopted 6/08

- CRN members will refrain from marketing the DHEA products that they manufacture or market under their brands as providing a general anabolic steroid-like response (muscle enlargement, increased strength, etc.).
- CRN members will not target those under 18 years old in their marketing or advertising of their DHEA-containing products, as this ingredient is unlikely to provide performance-enhancing benefits in this population.

Ephedra

Effective 03/01; rescinded 2/04 to comply with 21 CFR 119 that becomes effective 4/12/04, declaring dietary supplements containing ephedrine alkaloids to be adulterated because they present an unreasonable risk of illness or injury.

Niacin

Effective 9/99

Note: These recommendations pertain to only nicotinic acid, including sustained-release forms, and not to nicotinamide.

For immediate-release (crystalline) niacin (nicotinic acid):

CRN recommends that member companies adopt a maximum dosage level not to exceed 500 mg per unit-dose or per day for immediate-release niacin supplement products.

CRN recommends that member companies adopt the following precautionary label, or its equivalent, for immediate-release niacin supplements marketed in doses exceeding 100 mg per unit-dose:

CAUTION: FOLLOW LABEL DIRECTIONS. Do not take more than 500 mg of niacin per day or switch to more than 250 mg of sustained release niacin per day, except under supervision of a physician.

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CRN also recommends that member companies adopt the following informational label statement, or its equivalent, for immediate-release niacin supplements marketed in doses exceeding 35 mg:

NOTICE: Use of this product may cause skin flushing, burning, itching, or rash. Do not take on an empty stomach.

For sustained-release niacin (nicotinic acid): CRN recommends that member companies adopt a maximum dosage level not to exceed 250 mg per unit-dose or per day for sustained-release niacin supplement products.

CRN also recommends that member companies adopt the following cautionary label, or its equivalent, for sustained-release niacin supplements exceeding 50 mg:

CAUTION: FOLLOW LABEL DIRECTIONS. Do not take more than 250 mg of sustained-release (slow-release, time-release) niacin per day, except under supervision of a physician.

CRN further recommends that member companies be aware of the amount specific effects of the sustained release technology and niacin dose in their products, and if appropriate include a label NOTICE of a possible flushing effect.

Kava

Effective 3/02; revised 7/02 and 2/04

CRN's "Proposed Elements for a Voluntary Cautionary Label for Kava Products" are based on a CRN process of scientific assessment, consultation and coordination with FDA, other trade associations, and outside scientific advisors. CRN members should understand that neither FDA, CRN, nor any other assessment has suggested that scientific evidence has established a causal relationship between kava consumption and liver problems. Thus, CRN's recommendation is seen solely as a matter of ample prudence.

Suggested Elements of Voluntary Label For Kava Products:

- The US FDA advises that a potential risk of rare, but severe, liver injury may be associated with kava-containing dietary supplements.
- Ask a health care professional before use if you have or have had liver problems, frequently use alcoholic beverages, or are taking any medication.
- Stop use and see a doctor if you develop symptoms that may signal liver problems, including jaundice (yellowing of the skin or whites of the eyes) and brown urine. Other nonspecific symptoms can include nausea, vomiting, light-colored stools, unusual tiredness, weakness, stomach or abdominal pain, and loss of appetite.
- Not for use by persons under 18 years of age, or by pregnant or breastfeeding women.
- Not for use with alcoholic beverages.
- Excessive use, or use with products that cause drowsiness, may impair your ability to operate a vehicle or heavy equipment.