



RECOMMENDED GUIDELINES:

Labeling and formulation of melatonin-containing dietary supplements for sleep support

BACKGROUND:

Melatonin is a naturally occurring hormone made by the pineal gland which helps to control sleep and wake cycles. It is a dietary ingredient present in dietary supplements used for sleep support.

The safety of melatonin supplementation in various dosage formulations has been assessed in numerous clinical studies, as well as by authoritative and regulatory bodies. The Institute of Medicine draft prototype monograph for melatonin indicates that for healthy adults, short-term use of melatonin in amounts of 10 mg or less per day does not raise concern of harm,¹ and the Health Canada monograph for oral melatonin provides a dosing range of 0.1 to 10 mg per day.^{2,3} However, the majority of published safety data are from clinical studies in which melatonin was administered in amounts up to 5 mg per day.

CRN supports and encourages responsible marketing of dietary supplements. Therefore, CRN has developed scientifically-based voluntary guidelines that address serving size recommendations determined from safety information and label advisories for melatonin-containing dietary supplement products marketed for sleep support.

CRN recommends that its members follow these voluntary guidelines for their products marketed for sleep support⁴ that contain melatonin, and encourages all dietary supplement producers and marketers to follow these recommendations.

¹ IOM, 2004. Institute of Medicine Committee on the Framework for Evaluating the Safety of Dietary Supplements. Prototype monograph on melatonin. Dietary Supplement Ingredient Prototype Monographs, Developed as Examples for the Report *Dietary Supplements: A Framework for Evaluating Safety*. Institute of Medicine and the National Research Council of the National Academies, Washington (DC): National Academies Press 2004: D1-D71.

² Health Canada, 2013. Monograph: Melatonin – Oral. <http://webprod.hc-sc.gc.ca/nhp/nd/bdipsn/monoReq.do?id=136&lang=eng>

³ For all uses except jet lag (dosing range specifically for jet lag is 0.3 to 10 mg per day).

⁴ Products marketed for other purposes are outside the scope of these guidelines.

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VOLUNTARY GUIDELINES:

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

A. Serving Size Recommendations

The serving size should provide not more than 10 mg melatonin as per stated labeling per day when used in accordance with the directions for use.

B. Label Advisories for Conditions of Use

Product labels should include, but are not limited to, the following statements or similar language:

- Consult a healthcare professional:
 - If you are experiencing long-term sleep difficulties.
 - Before use in children.
 - Before use in pregnant or nursing women, those with a medical condition, and those taking medication.
- Do not drive or operate machinery when taking melatonin.

C. Implementation

CRN recommends its members comply with these guidelines for new product labels put into the marketplace as soon as practicable, given the realities of label stock, potential formulation changes and distribution chains, but no later than 12 months after the effective date.

Effective Date: June 18, 2015