

Increasing public health awareness of magnesium: one step at a time

Rebecca B. Costello, Andrea Rosanoff

CMER Center for Magnesium Education and Research, Pahoehoe, HI 96778, USA

Correspondence

<rbcostello@earthlink.net>

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The Food and Drug Administration (FDA) monitors health claims on foods and dietary supplements in the USA. According to the FDA definition, a health claim recognizes the relationship between a substance and a disease or health-related condition, particularly the relationship between that substance and a reduction in the risk of contracting that particular disease or health-related condition. The substance must be associated with a disease or health-related condition for which the general US population, or an identified US population subgroup, is at risk. Once approved through the FDA review process, manufacturers of eligible foods and dietary supplements are allowed to place health claims on their products' labels [1].

In 2014, researchers of the Center for Magnesium Education and Research (CMER) were discussing how best to fulfil the CMER's mission. Dr. Rebecca Costello suggested that having a US government agency "officially pass approval" on an aspect associated with magnesium would be worth a substantial effort. We decided to apply to the FDA for a health claim for magnesium for hypertension (blood pressure). At that time, almost half of US adults were estimated to have high blood pressure, and the CMER has been studying and collaborating on aspects of magnesium and hypertension since 1998 [2-8].

The FDA has strict guidelines for petitioners of health claims, thus health claim applications are rare, expensive, and time-consuming and require an exhaustive review of the literature and guidance by a knowledgeable consultant. Nonetheless, the CMER spearheaded the effort, which culminated in the August 16th, 2016 submission

of a 156-page application to the FDA entitled: "Petition for the Authorization of a Qualified Health Claim for Magnesium and Reduced Risk of High Blood Pressure (Hypertension)" [9].

After more than five years, the FDA approved a "Qualified Health Claim for the Consumption of Magnesium and Reduced Risk of High Blood Pressure (Hypertension)" on January 10th, 2022 [10]. Magnesium now has its first health claim issued by the FDA which is one of only three qualified health claims for blood pressure, along with eicosapentaenoic acid and docosahexaenoic acid approved in June 2019 [11] as well as calcium for hypertension, pregnancy-induced hypertension, and preeclampsia, approved in October 2005 [12]. Manufacturers of foods and/or dietary supplements may now use one of the following statements on their products if they meet certain criteria (see below) to describe the relationship between magnesium and high blood pressure:

- "Inconsistent and inconclusive scientific evidence suggests that diets with adequate magnesium may reduce the risk of high blood pressure (hypertension), a condition associated with many factors."
- "Consuming diets with adequate magnesium may reduce the risk of high blood pressure (hypertension). However, the FDA has concluded that the evidence is inconsistent and inconclusive."
- "Some scientific evidence suggests that diets with adequate magnesium may reduce the risk of high blood pressure (hypertension), a condition associated with many factors. The FDA has concluded that the scientific evidence supporting this claim is inconsistent and not conclusive."

As for these acceptable claims, a qualified health claim must be accompanied by qualifying language on the product label. The FDA concluded in their safety review that for the use of the qualified health claim on dietary supplement labels, the product must contain >85 mg magnesium but not more than the upper limit of 350 mg magnesium per serving. Food products using this health claim must contain at least 85 mg magnesium per serving (20% of the Daily Value (DV)) for magnesium, which is 420 mg). Foods must also meet the FDA's disqualifier levels for health claims of <480 mg sodium, <13 g total fat, <4 g saturated fat, and <60 mg total cholesterol, as well as include one or more of the following nutrients at 10% DV per serving: fibre, protein, iron, calcium, potassium, or vitamin D. Nuts were specifically exempt from the need to have <13 g total fat, as requested in the CMER's original petition, as many nuts are approved to carry a health claim for reduced risk of coronary heart disease.

As stated by Andrea Wong, PhD from the CRN, "We are pleased that the FDA recognizes the role of magnesium in reducing the risk of hypertension". The CMER is also encouraged by this FDA action but emphasizes the great need for official recognition by public health agencies of the importance of magnesium for overall health in today's global societies and the need for its proper assessment. The official daily requirements of magnesium are in need of review and updating [13], in particular, to avoid increased chronic latent magnesium deficiency that may result from rising global human body weight [15], which is now known to raise magnesium requirements [14].

In 2013, the CMER also worked with colleagues across the USA to nominate magnesium to the US and Canadian governments as a nutrient needing updating by the Food and Nutrition Board (FNB) at the Institute of Medicine of the National Academies through the Dietary Reference Intake (DRI) process. Sixteen nutrients were nominated for review and/or updating. Four prioritized nutrients were selected: sodium, omega-3 fatty acids, vitamin E, and magnesium [16, 17]. The DRIs for sodium and potassium have been reviewed and updated [18], but vitamin E and magnesium have been deferred in support of a DRI review on macronutrients and energy. Unfortunately, this puts official updating of

magnesium requirements in North America again on the "back burner."

We hope the FDA issuance of the Magnesium for Blood Pressure Qualified Health Claim will be a first step in the long and pressing need to update requirements, as well as serum magnesium reference ranges and other needs, in order to improve public health.

Disclosure

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Conflict of interest: none. (CMER, Center for Magnesium Education and Research is a non-profit collegium of scientists dedicated to the health of humankind by promoting knowledge of nutrient magnesium and its peer-reviewed science.)

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