

SAFEGUARDS

CONSUMER GOODS AND RETAIL

FOOD

NO. 101/14 MAY 2014

US FDA PROHIBITS SOME LABELLING CLAIMS FOR OMEGA-3 FATTY ACIDS (DHA, EPA AND ALA)

On 28 April 2014 the United States Food and Drug Administration (US FDA) published a final rule prohibiting certain nutrient content labeling claims for docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and alpha-linolenic acid (ALA) omega-3 fatty acids. This final rule is not substantially different than the proposal published in 2007.¹

CERTAIN NUTRIENT CONTENT CLAIMS PROHIBITED FOR DHA, EPA AND ALA²

The US FDA will prohibit DHA and EPA nutrient content claims such as “high in”, “rich in” and “excellent source of” and other similar claims on food and dietary supplement labels. The US FDA is prohibiting some such claims for ALA but at this time will continue to allow the claims noted in table 1 to remain on labels in the market providing the conditions are met.

Table 1.-Nutrient Claims

Nutrient Content Claim for ALA	Conditions For Making the Claim ¹
High	≥ 320 mg of ALA per RACC (≥ 20% of 1.6 g/day)
Good Source	≥ 160 mg of ALA per RACC (≥ 10% of 1.6 g/day)
More	≥ 160 mg of ALA more per RACC than an appropriate reference food (≥ 10% of 1.6 g/day)

¹ Nutrient content claims must comply with all applicable FDA regulations regarding the making of such claims.

US FDA is prohibiting these claims because they have not established nutrient content levels by regulations. The US FDA will allow product claims if certain requirements are met, such nutrient levels can be based on authoritative statements published by certain types of scientific bodies, such as the Institute of Medicine of the National Academies (IOM). The claims listed in Table 1 are being allowed by the US FDA because they are authoritative statements from a scientific body recognized by the US FDA.

Effective date of this rule is January 1, 2016.



¹ [Food Labeling](#)

² [Omega-3 Fatty Acids](#)

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