

For Immediate Release

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**AstaReal, Inc. Responds to Misleading BGG North America Announcement –
There are No “FDA-Allowed Structure / Function Claims;”
Calls for the Industry to be Cautious**

BURLINGTON, NJ – AstaReal, Inc., which sells astaxanthin under the brand name, AstaReal, has issued a caution to retail manufacturers of their legal obligations to evaluate their astaxanthin label claims based on the facts and their own substantiation reviews. The caution has been issued in response to a news release disseminated in mid-May by BGG North America Inc. and/or its affiliated entity, Algae Life Sciences, Inc. (collectively, “BGG”) asserting its astaxanthin ingredient AstaZine has attained the “landmark achievement” of procuring “239 FDA-Allowed Structure/Function Claims” through the mere act of sending the agency a notification. In fact, there are already more than 100 such notifications on file with the FDA for a variety of structure/function claims submitted by dozens of companies marketing astaxanthin-containing products to retail consumers.

Joe Kuncewitch, National Sales Manager of AstaReal, Inc., explained, “It is our understanding that the FDA does not ‘allow’ the use of structure/function claims merely because a company submitted a notification letter, and that the receipt or non receipt of a ‘courtesy letter’ does not in any manner indicate that a submitted claim has been ‘allowed’ by the FDA.”

Kuncewitch added, “Our experience, under the regulatory structure, is that the FDA requires that a notification be submitted for each ‘brand name’ label that will carry the claim, such that an ingredient supplier submitting a generalized structure/function notification to FDA that does not include the specific brand name is a meaningless act.” FDA, itself, has stated:

[I]t cannot be assumed that the first submission for a claim under section 403(r)(6) of the act establishes that adequate substantiation exists to support that claim for all products that may contain that substance. Each manufacturer must have its own substantiation that any statement it makes in the labeling of a dietary supplement product under section 403(r)(6) of the act is truthful and not misleading, and the manufacturer must submit a notice to FDA that attests to this fact.

62 Fed. Reg. 49883 (September 23, 1997).

As further stated by FDA, “[t]he manufacturer must have substantiation that the statement is truthful and not misleading.” *Id.* at p. 49884. Kuncewitch noted, “In our experience, by ‘manufacturer,’ FDA is referring to the company whose name appears on the retail consumer label.” Therefore, Kuncewitch advised that a good place to start would be the FTC rules for claim substantiation. “Also, keep in mind that if the structure function claim(s) on your retail product label(s) are ever challenged by the FTC or

FDA or any state AG or class action initiative . . . you will be on our own," he cautioned. "Your ingredient supplier is not likely to be named in the action. So, before any consideration regarding the supposed 'landmark achievement' of 239 claims for astaxanthin, do your homework and consult legal counsel."

In addition, BGG cites to certain research per its published article, "Medical Research Abstracts on Astaxanthin," but that article cited to numerous studies – not on its particular brand – but instead, studies that were conducted by others, including AstaReal/Fuji, and were brand-specific as to AstaReal astaxanthin. Not only does this article lift verbatim language from AstaReal's studies, but it camouflages this fact by apparently omitting any attribution to AstaReal/Fuji.

Dr. Arun Nair, President of AstaReal, Inc., emphasized, "AstaReal astaxanthin has over 120 published studies using our branded AstaReal astaxanthin and of these, more than 50 of the studies are human clinicals. With over 20 years of experience in the astaxanthin space, AstaReal is committed to inform customers and the public with credible and accurate information."

Kuncewitch concluded, "In our view, what makes an ingredient supplier a 'leader' is the amount of brand specific substantiation it can provide to its customers."

About AstaReal

AstaReal is a part of the Fuji Chemical Group of Japan. AstaReal produces natural astaxanthin from algae cultivated at facilities in Sweden and the USA with sales offices in Japan, Sweden, USA, Singapore, and India.