

Top Formulator Exonerated in FTC Case

Many US businesses caught up in regulatory tug-of-war with FDA, FTC and US Congress.

Top US product formulations expert Mr. Brazos Minshew and his Native American Legacy Corporation, Samuel J. Brant, LLC were excluded from prosecution in the long running Federal Trade Commission (FTC) case against XXL Impressions and Synergixx CTF Media (Case Number 1:17-cv-0067-NT In the United States District Court for The District of Maine). Both companies were unrelated to Mr. Minshew and Samuel J. Brant, LLC. Mr. Minshew was named in the original complaint for his brief involvement as an unpaid formulations advisor to XXL Impressions. However, he was later excluded from the prosecution of this case after it was found that his consent to endorse only products that have randomized, double-blind placebo controlled human clinical trials on the finished combination satisfied the concerns of the FTC. The terms of the settlement between Mr. Minshew and the FTC completely exonerate Mr. Minshew from any claims of fraud levelled against XXL Impressions and Synergixx CTF Media.

The case against XXL Impressions and Synergixx CTF Media exemplifies the struggle between the United States Congress and the U.S. Food and Drug Administration (FDA). In the Dietary Supplement Health and Education Act (DSHEA) of 1994 the US Congress clearly defined the ability of individuals or corporations to disseminate truthful information about nutritional supplements. Since the approval of DSHEA, the FDA has consistently attempted to re-define the law concerning nutrients with an increasingly narrow scope. Regarding this conflict, the FDA published the following statement:

“The agency does not agree, however, that section 403(r)(6) of the act authorizes dissemination of any and all information about dietary supplements without prior review. The agency also disagrees with the assertion that separate congressional authority is needed for this rulemaking.”

(Retrieved from: <https://www.fda.gov/ohrms/dockets/98fr/010600a.txt>)

At the center of the case against XXL Impressions and Synergixx CTF Media is the assertion that a product containing a combination of nutrients does not qualify to make statements allowed for the individual nutrients in isolation. According to the FDA, “acceptable structure/function claims [such as] ‘mild memory loss associated with aging’” may be made for a single ingredient with credible evidence to support the claim. However, the FTC may consider this claim fraudulent if applied to products containing multiple ingredients without clinical trials on the final ingredient combination. (Retrieved from:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/uc...>
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The struggle continues between the US Congress and the FDA “to bring common sense to the treatment of dietary supplements under regulation and law.”

(Retrieved from: <http://www.health.gov/dietsupp/ch1.htm>)

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