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FDA seizes over \$71k in products

By Clarisse Douaud

10/15/2007 - **The US Food & Drug Administration (FDA) last week showed potential false marketers of dietary supplements that it means business when it requested US Marshals to seize approximately \$71,000 of goods from Fullife Natural Options in Florida.**

Based in Boca Raton, the company marketed and distributed [Charantea](#) Ampalaya capsules and Charantea Ampalaya tea for use in treating serious conditions, such as diabetes, anemia, and hypertension.

The federal authority said this is the second such enforcement action taken at its request in the past two months against dietary supplements being promoted with drug claims to cure or treat diabetes and other conditions.

This complaint - filed by the US Attorney's Office for the Southern District of Florida - charges Fullife's products violate the drug and misbranding provisions of the Federal Food, Drug and Cosmetic Act.

Before a new drug can be legally marketed, it has to be shown to be safe and effective, and approved by [FDA](#). As such, the agency considers the Charantea products as unapproved new drugs because of the claims made relating to the prevention or treatment of diseases.

FDA refers to claims as they are made on the products' labelling, promotional literature and web site.

"The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease," wrote Joseph Baca, from the Center for Food Safety and Applied Nutrition, to marketers in an October 2006 warning letter. *"The marketing of this product with these claims violates the Act."*

FDA did not respond to NutraIngredients-USA.com for further information on how it first came across Fullife's marketing practices.

Despite the agency's warnings, Fullife failed to comply and FDA found that the offending claims were still being made.

Some of the claims made by Fullife and cited by FDA, include ones made in testimonial format:

- "Charantea helps me lower my blood sugar level naturally."

- "With Charantia fortifying my diet, my doctor is able to reduce my medication."

- "It is also our experience that in most cases, after a few days or within a month after our diabetic patients starts drinking Charantia tea to fortify their usual daily diet, regular exercise and medication, their blood sugar goes down to an even lower level than before, there is less sharp rises [sic] or 'spiking' and it remains more

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stable for longer periods of time."

In August of this year - once again at FDA's request, and in Florida - US Marshals seized approximately \$41,000 worth of stock for Glucobetic, Neuro-betic, Ocu-comp, Atri-oxi, Super-flex, MSM-1000, and Atri-E-400 capsules. These were being distributed and promoted by Tallahassee-based Charron Nutrition for use in treating diabetes, arthritis and other serious health conditions.

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