



Sant'ANGELICA®

**Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C. Street, S W
Washington, DC 20204**

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Turin, 18th May 2001

Dear Sirs,

Notice is hereby given pursuant to the requirements of Section 403 (r) (6) (21 U.S.C. §343 (r) (6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR §101.93, that Medestea Internazionale S.r.l., located in Turin, Via Magenta 43, Italy intends to market a dietary supplement CELLULASE® Gold.

Cellulase Gold contains the following ingredients: Lipovascolen™, [Grape seed extract (vitis vinifera), Bladderwrack extract, Centella asiatica extract (leaves), Ginkgo Biloba extract (leaves)], Sweet clover (Melilotus officinalis) extract (flowering tops), Ruscus aculeatus extract (rhizome). RECAPTA™ [Fish oil, Borage oil (seeds), Vitamin E, Lipoic Acid, d-limonene, Policosanols, Vitamin B6, Piper nigrum dried extract, Vitamin B12, Folic acid].

It bears the following statement(s) on the label and/or in the labelling:

- ...Helps reduce cellulite...
- ...Helps prevent cellulite...
- ...Deal with cellulite at its source...
- ...Works below the surface of your skin where cellulite begins.
- ...Scientifically formulated to help reduce cellulite.
- ...Works over time at the source of the problem to reduce cellulite.
- ...Increase blood circulation, reduce fluid build up, stimulate metabolism and reduce localised fat.
- ...Antioxidant, free radical scavengers.
- ...Naturally increases cell membrane fluidity.
- ...Helps keep your cells and body younger.

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The undersigned certifies that the information contained in this notice is complete and accurate and that Medestea Internazionale s.r.l. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a) (1) two copies of this notification are enclosed.

Sincerely,

Cinzia Pranzoni, Ph.D.
Senior Product Development Scientist

Antonio Soleti, Ph.D.
Senior Clinical trials co-ordinator

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