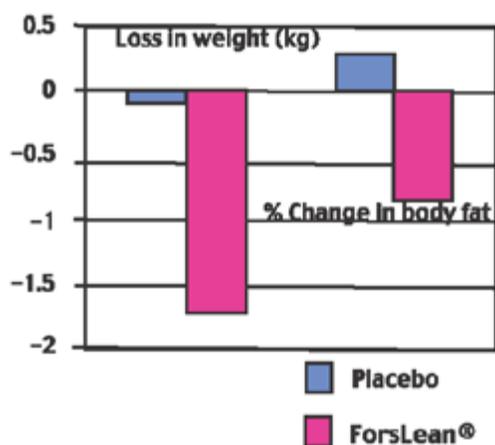


New Clinical Trial Establishes The Safety and Efficacy of ForsLean®

A double blind and randomized study was performed at the Shri C. B. Patel Research Center for Chemistry and Biological Sciences in Mumbai, India. The subjects included 60 obese male and female volunteers aged 25-45 with a body mass index (BMI) between 28 and 40 and/or body fat concentration above 30 percent in males and 40 percent in females. Participants were either given 250 mg of Forslean® (standardized to 10 percent forskolin) approximately 30 minutes before meals twice daily or a matching placebo.



Volunteers who received Forslean® lost an average of 3.81 pounds or 2.3% of their total body weight, while the placebo group gained an average of less than one half pound or 0.29% of their total body weight. Additionally, volunteers who received the placebo gained 0.32% body fat, while individuals receiving ForsLean® lost 0.87% body fat

which was replaced by lean body mass.

It was observed that the levels of all three thyroid hormones remained within normal range in both Forslean® and placebo treated groups after 12 weeks of the regimen. Those volunteers receiving Forslean® showed a significant rise in the serum concentrations of HDL at the end of the study, while triglyceride, total cholesterol, LDL and VLDL levels remained unchanged in this group, as compared to baseline and placebo group levels. There was no significant change in the diastolic and systolic blood pressure in both Forslean® and placebo treated groups.

Results suggest that ForsLean® reduces body weight and body fat, and helps augment lean body mass. The 12 week treatment did not produce any subjective or objective side effects in either Forslean® or placebo receiving groups. The active group showed increase in serum levels of HDL and significant decrease of total cholesterol/HDL ratio as compared to the control group. No untoward effects on thyroid hormones, blood lipid profile and other parameters was observed.



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Profile: Dr. Samuel Meyer, President Business Development

Dr. Samuel Meyer recently joined Sami Labs Ltd., Sabinsa's manufacturing and research group in India. Dr. Meyer holds a MD in Pediatrics from the University of Bombay, India. He brings with him over 35 years of medical research and leadership experience in the pharmaceutical industry. He began his career as a medical researcher at Hoechst India (now Aventis) in 1967 and rose to the position of Medical Director. During his 25 years tenure at Hoescht, he was involved in the discovery and introduction of a number of leading therapeutic drugs to the Indian as well as global markets. This included the development of over 25 NDAs (New Drug Applications). Subsequently, Dr. Meyer was Senior Vice President, Business Development at Cadila Health Care for over 6 years.

Dr. Meyer has served as a medical expert on various governmental and non-governmental committees, and on executive committees of a number of professional societies and associations. He guided the publication of the first "National Essential Drug List of India," and was Vice-Chairman (Medical) of the Organization of Pharmaceutical Producers of India (OPPI), Chairman (Medical) of Indian Drug Manufacturers Association (IDMA), and was the founder secretary of the Chronobiological society of India. Dr. Meyer has been a visiting lecturer at universities in India and abroad and has authored and peer-reviewed several publications, particularly in the area of Drug Research and Development.

At Sami Labs, Dr. Meyer will work on developing and implementing IND (Investigational New Drug) applications for various products and formulations.

Ind Applications By Sami Labs Ltd

1. Forskolin Eye Drops:

Scientists at Sami Labs Limited have developed a stable formulation of forskolin eye drops for use in the management of ocular hypertension and glaucoma. The company is in the process of filing an Investigational New Drug (IND) application for this product in India . Hoechst India Ltd (now Aventis) had originally filed an IND application for evaluating forskolin eye drops for the same indication viz. ocular hypertension and glaucoma, in 1983. Sami Labs will be the second applicant, and plans to conduct multicenter clinical trials (in 6 centers with a total of at least 100 patients) as part of the IND protocol.

Forskolin is insoluble in water and therefore difficult to formulate into clear compositions for ocular application. The patent pending forskolin eye drops composition from Sami Labs contains natural forskolin from *Coleus forskohlii* solubilized in water using an innovative method.



2. Psoriasis support composition

Scientists at Sami Labs developed a patent pending combination treatment for psoriasis. The regimen entails internal administration of a phytonutrient-mineral composition along with the application of a topical cream containing selected phytonutrients.

Preliminary laboratory data were encouraging and an IND application for this regimen is in the process of being filed in India. Multicenter trials on at least 100 psoriasis patients form part of the protocol. The study will be conducted at centers in various climatic zones in the country, to enable determining the efficacy of the formulation in subjects exposed to diverse atmospheric temperature and humidity parameters

COSMETIC CORNER - 2005 Preview

The spirit of innovation at Sabinsa is as strong as ever as evidenced by the pending launch of our new product - SabiWhite™.

SabiWhite™ is Tetrahydrocurcumin - a single entity, color free compound derived from yellow curcuminoids extracted from *Curcuma longa* (turmeric).

SabiWhite™ has proven antioxidant and anti-inflammatory properties. It is a powerful luminosity booster and tyrosinase inhibitor. It also has UV protectant properties.

Antioxidant Action: SabiWhite™ acts by preventing free radical formation and by quenching preformed radicals and was shown to be superior to vitamin C and TROLOX.

Luminosity Boosting and Tyrosinase Inhibitory Action: Research by Sabinsa shows that:

- SabiWhite™ is a more efficient tyrosinase inhibitor than Kojic acid
- As compared to other actives, very low concentrations of SabiWhite™ are needed to effect equivalent tyrosinase inhibitory action (skin lightening)

Anti-inflammatory and UV Protectant action: SabiWhite™ inhibits metalloproteinase and cyclooxygenase enzymes which play a major role in premature aging and inflammation.

SabiWhite™ is sparingly soluble in oil and freely soluble in methyl benzoate, N-methyl pyrrolidone and ethanol. Suggested level in formulations is 0.1 to 2.0%. Safety testing showed no untoward effects on the skin.

For more information please write to tasneen@sabinsa.com.



PRODUCT ADS

Look for Sabinsa Ads in the following publications:

HAPPI, Soap Perfumery & Cosmetics, Cosmetics & Toiletries, Natural Products Insider, Whole Foods Magazine, Nutrition Industry Executive, Functional Foods & Nutraceuticals, Nutraceuticals World & Nutritional Outlook