What We Know About FBCx®
May 1, 2007

What is FBCx:-
- FBCx® is an all natural soluble fiber derived from non-GMO corn that has the unique ability to bind nine times its own weight in dietary fat.
- Taken as directed six tablets per day is sufficient to decrease your daily caloric absorption by about 500 kilocalories or about 25-30% of the typical American diet. Five hundred kcal per day becomes 3,500 kcal/week which equates to a weight loss of about 1-1½ pounds per week or 4-6 pounds per month.
- FBCx is more efficacious than any other nutraceutical or pharmaceutical on the market.
- There is no “program” or special diet involved with taking FBCx; simply eat a reasonable, normal or high fat-containing diet, be compliant and do not use FBCx as a license to over eat, and you will lose weight.
- There are no known negative side effects except for gas if you take it without having fat in your meal.
- Positive side effects include:
  - Lower blood LDL (bad) cholesterol levels
  - Lower blood triglyceride levels
  - FBCx preferentially removes saturated and trans (bad) fats from the diet
  - Increased insulin sensitivity
  - Increased leptin sensitivity – increased satiety
  - Improved glycemic index of foods and improved glycemic control
  - Resolves chronic diarrhea and constipation immediately

Published Findings:
First Animal (Rat) Study: A controlled study conducted at Wayne State University. Relative to control animal group on a high-fat diet:
- FBCx prevented weight gain.
- FBCx lowered the serum triglyceride levels by 30%. There are no nutraceutical or pharmaceuticals that we are aware of that elicit such a dramatic effect on blood fat levels.
- FBCx lowered the blood serum leptin levels, indicating an increase in leptin sensitivity and therefore satiety. Decreased leptin sensitivity leads to over eating.
- FBCx appears to have increased insulin sensitivity, which may delay the onset of type 2 diabetes.
- FBCx increased fecal fat excretion, indicating that fat passed through the gut without being metabolized.
- FBCx was shown to bind and remove 9 times its own weight in dietary fat.
- FBCx produced no adverse side effects.


First (Human) Clinical Trial: This 3-month double-blind, placebo-controlled clinical trial with obese
(BMI>30) diabetic patients of The Grunberger Diabetes Institute demonstrated that:

- FBCx is effective at reducing and/or maintaining body weight in patients with type 2 diabetes.
- Nutritional counseling would enhance the benefits of FBCx.
- FBCx lowered both triglyceride and LDL (bad) cholesterol levels in those patients who began the study with elevated triglyceride levels.
- FBCx significantly increased the blood levels of adiponectin, indicating an increase in insulin sensitivity and therefore a possible delay in the need to institute or the intensity of insulin therapy in these type 2 diabetic patients.
- FBCx, based upon dietary recall data, was shown to bind and remove 9 times its own weight in dietary fat.
- FBCx appears to preferentially bind saturated over unsaturated dietary fats.
- FBCx produced no adverse side effects.

Grunberger G, Artiss JD, Jen K-LC. Beneficial Effects of a New Soluble Dietary Fiber FBCx™ in Obese Patients with Type 2 Diabetes. *Diabetes*, 54(Supl.1); A440:2005.


**Second Animal (Mouse) Study:** A 14-week controlled study conducted at the National Institutes of Health with mice that have a predisposition to developing very high levels of fats in the blood. Relative to control animal group on a high-fat diet:

- FBCx is efficacious in reducing blood cholesterol in the pro-atherogenic VLDL, LDL and IDL (bad cholesterol) lipoprotein fractions while leaving the anti-atherogenic HDL (good cholesterol) lipoprotein levels unchanged.
- FBCx appears to improve the blood fatty acid profile by preferentially decreasing the trans and saturated relative to unsaturated fatty acids. We are not aware of any other nutraceutical or pharmaceutical that has demonstrated this phenomenon.
- FBCx lowered blood cholesterol levels by 15% and triglyceride levels by 23%.
- FBCx may be beneficial in the management of hyperlipidemia (elevated blood fat levels) and possibly reducing the risk of developing cardiovascular disease.


**Animal (Rat) Fecal Saturated Fat Excretion Study:** Controlled rat study performed at the University of Minnesota looking specifically at the effects of alpha-cyclodextrin (FBCx) on fecal fat excretion and in particular at differences between saturated and unsaturated fats.

- Relative to cellulose (vegetable fiber) FBCx had no effect on unsaturated fat excretion.
- FBCx increased the excretion of saturated fat 16-times relative to cellulose.
- FBCx is significantly more effective than chitosan.

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1 Please note that we are very pleased that the FDA has adopted recommendations for weight loss studies that are consistent with our study design (see [http://www.fda.gov/ohrms/dockets/98fr/03d-0570-gdl0001.pdf](http://www.fda.gov/ohrms/dockets/98fr/03d-0570-gdl0001.pdf)).

Glycemic Response Clinical Trial: A double-blind, randomized, cross-over study into the effects of alpha-cyclodextrin (FBCx) on blood insulin and glucose levels following a zero fat high carbohydrate meal. Relative to the control population, alpha-cyclodextrin at levels 2½ times greater than the dose recommended by ArtJen:

- FBCx significantly lowered post meal levels of blood glucose. Elevated levels of glucose following meals have been shown to increase the risk of developing type 2 diabetes, cardiovascular disease and some types of cancers.
- Blood insulin levels were not affected.
- FBCx increased satiety.
- In the absence of fat, FBCx caused gastrointestinal discomfort.


Pre-Clinical Findings: As our sales of FBCx grows, we receive comments from customers that are not clinically proven but are consistent with some of our studies and with what is known about lipid metabolism and the effects of soluble fibers in general.

- Numerous customers have informed us that the chronic diarrhea that they have suffered with for up to 15 years stops immediately. The diarrhea that they mentioned is typically due to IBS (irritable bowel syndrome), chronic pancreatitis or gall bladder removal.
- Several customers have told us that their chronic constipation is immediately resolved.
- Several customers have reported weight losses on the order of 60 pounds in three months.
- Decreases in blood cholesterol levels of 20% and triglyceride levels of 20-40% have been reported.
- One recent customer claims that within one week, FBCx was having a positive effect on the eczema on her face.

Competing Products:-

- Nutraceuticals:
  - There are, to the best of our knowledge, no non-prescription weight loss products other than FBCx that have been demonstrated in the peer-reviewed, tier-one scientific/medical literature to have any effect on weight loss or weight management. The one exception to this rule are the ephedra/amphetamine based products that have been ruled unsafe by the FDA.
  - There are, to the best of our knowledge, no non-prescription products other than FBCx that have been demonstrated in the peer-reviewed, tier-one scientific/medical literature to have any effect on blood lipid, leptin or insulin levels.

- Pharmaceuticals:
  - Sibutramine: Sold by Abbott Laboratories under the trade name Meridia. The mechanism is not well understood but it appears to be affecting brain neurotransmitters. It carries with it many side effects (see [http://www.nlm.nih.gov/medlineplus/encyclopedia.html](http://www.nlm.nih.gov/medlineplus/encyclopedia.html)) and is FDA approved with no more than 2 years of continuous use. Weight loss relative to the...
control population is less than 2% after 52 weeks, note that both test and placebo groups were on hypocaloric diets.

- Orlistat: Sold by Roche under the trade name Xenical, and will be released by GlaxoSmithKline in a lower dose as Alli in June 2007. This is a lipase (digestive enzyme) inhibitor that allows about 1/3 of the dietary fat to pass through without being absorbed. UNLIKE FBCx this unabsorbed fat is available for the microbes in the large bowel to metabolize it. The metabolism in the large bowel causes severe diarrhea, oily stools and "leaking" (see [http://www.nlm.nih.gov/medlineplus/encyclopedia.html](http://www.nlm.nih.gov/medlineplus/encyclopedia.html)). These side effects can be alleviated by consuming a low fat, low calorie diet; thus this drug acts as forced behavior modification. Clinical trials indicate results similar to Sibutramine.

- Rimonabant: Sold by Sanofi-Aventis under the trade name Acomplia has not received FDA approval for sale within the USA, but is available in the EU. This drug has caused a lot of stir because it specifically targets brain cannabinoid (pot) receptors; based upon the observation that pot users get the munchies. Efficacy is about the same as the two above, however, the side effects are rumored to include severe depression and suicidal tendency. Some observers state categorically that the lack of efficacy and serious side effects will stop it from receiving FDA approval.