Insulin Overview

**Introductory Information**

The fasting insulin test is performed to determine the baseline level of insulin in the serum. This is one of our favorite topics as we believe excessive amounts of insulin in the blood is a major negative influence on American health and there is plenty of supporting research. Insulin resistance, hyperinsulinism, Syndrome X and Cardio-Metabolic Syndrome are common terms used to describe dysfunctions in glucose metabolism that are related to insulin.

Only in the last few years have we seen interest in insulin relating to anything other than diabetes. There are approximately 16 million Americans with diabetes; there are at least 50 million with Syndrome X as defined by JAMA in 2002 and that data was gathered over 10 years ago.

We will provide basic information on insulin and examine research on the implications of excess insulin along with possibilities for resolution in this issue of the PCS newsletter.

*From Medline Plus Medical Encyclopedia...*

Insulin is a hormone released from the beta cells of the pancreas. Insulin's most important function is to facilitate glucose (blood sugar) uptake by a variety of tissues, especially adipose (fat) and skeletal muscle. Insulin also stimulates the synthesis and storage of triglycerides and proteins. Insulin is the most important regulator of blood glucose. High blood glucose (such as exists shortly after a meal) stimulates the release of insulin, whereas low blood glucose levels inhibit insulin release. The most important reason for measuring the blood insulin level is the diagnosis or evaluation of hypoglycemia (low blood sugar). Also, insulin levels measured while fasting can give information about the body's sensitivity to insulin. High insulin, even with normal blood sugar, may indicate that the pancreas is working harder-than-normal to get the blood-sugar level down. This situation is usually caused by the body being resistant to insulin's effect -- a condition called "insulin resistance syndrome" or "metabolic syndrome." It is a very common feature of obesity and of hormonal problems such as polycystic ovary syndrome.

**Excerpts From Lab Corp’s Directory of Services...**

**Reference Range**: Adults: 6-27 µIU/mL

Insulin is protein hormone produced by the beta cells of the pancreas. It consists of two chains (A and B) connected by disulfide bridges. Insulin and C-peptide are produced by the pancreas as the result of proteolytic cleavage of proinsulin. Insulin is an anabolic hormone that stimulates the uptake of glucose into fat and muscle and promotes the formation of glycogen. Insulin stimulates protein synthesis and inhibits protein degradation. Glucose, amino acids, and certain pancreatic and gastrointestinal hormones (eg, glucagon, gastrin,
secretin) stimulate the pancreas to secrete insulin. Insulin secretion is inhibited by hypoglycemia and somatostatin. In healthy individuals insulin is secreted in a pulsatile fashion that is closely controlled by glucose levels. The primary clinical utility of insulin measurement is in the evaluation of patients with fasting hypoglycemia. Insulin levels tend to be inappropriately elevated in patients with insulin-secreting tumors. Fasting hypoglycemia in association with markedly elevated serum insulin levels is considered diagnostic for insulinoma. (In contrast with insulin resistance where glucose would be normal or elevated)

Circulating antibodies to insulin, both autoantibodies and antibodies to therapeutic insulin, can interfere with the immunoassays for insulin.

**Insulin, fasting**

**Optimal Value:** < 10 µIU/mL

**Ordering Code** 004333  **CPT Code** 83525

**Comment:** Our Optimal Value differs significantly from the laboratory Reference Range. I have spoken to a lab director at LabCorp regarding the establishment of reference ranges and I can tell you it is a complicated procedure. I am pleased to say they are making a substantial attempt to accommodate the need for health care as well as disease care. We have seen changes in a number of reference ranges based on current research and, in time, we expect to see more updates after due diligence is completed (see Extras for new vitamin D info). There is a great deal of responsibility in establishing reference ranges and I am pleased to say that LabCorp takes this very seriously. There is expectation and hope on our part that the insulin reference range with be scrutinized in the near future.

We are taking the position that the Optimal Value for fasting insulin should be less than 10 µIU/mL despite the fact that the average levels in America may be higher. Many experts on the subject, including Dr. Gerald Reaven who coined the term Syndrome X, endorse similar values. It should acknowledged that individual differences may allow some to have higher fasting insulin – if CRP, fibrinogen and the rest of the chemistry looks good, we wouldn’t advocate heroic measures to get fasting insulin below 10.

How we arrived at this value: from a common sense perspective, if the level of fasting glucose is acceptable and the Hemoglobin A1c corroborates that finding, then even flagged low insulin levels (< 5) are adequate to accomplish the job of regulating blood sugar. More is not better. In fact, research shows that more can be dangerous and a sign of insulin resistance.

**Related Laboratory Tests**
Fasting glucose, Hemoglobin A1c, Glucose Tolerance test (GTT), glycohemoglobin, C-peptide, C-reactive protein (high sensitivity/cardiac), HDL and LDL cholesterol, triglycerides, and numerous other tests relating to down-line disorders.

H A1c is a fraction of glycohemoglobin and is commonly used as a marker for long-term glucose evaluation. H A1c is red blood cell glycated hemoglobin (glucose/protein compound) and reflects the average glucose content for the last 60 days based on the typical life span of 120 days for red blood cells.

C-peptide is the protein to which insulin is attached, so regardless of the amount of insulin found in the blood, we know from looking at C-peptide exactly how much insulin was produced.

**Research Information**

**What Is Insulin Resistance?**
Under normal circumstances, a certain small amount of insulin is required to metabolize a given amount of glucose. When this amount of insulin is no longer able to accomplish this task, the pancreas releases more and more insulin in an effort to control glucose – the body has become resistant to insulin. This extra insulin is not innocuous.
Most everyone is aware that Americans consume in excess of 150 pounds of sugar each year and we will suggest this figure is underestimated because refined carbohydrates are often considered "grains". We simply overwhelm the body with too much glucose as opposed to the 1900’s when sugar intake was less than half what it is today.

What Health Care Issues Are Connected to Dysfunctional Glucose Metabolism and Insulin Resistance?

Weight gain, fatigue, diabetes, elevated cholesterol and triglycerides, hypertension, atherosclerosis, fatty liver disease, polycystic ovary disease, candida/mycotoxins, acidic pH, magnesium loss, calcium-phosphorus imbalance, a pro-coagulation state with excess fibrinogen and a systemic pro-inflammatory state with increased IL-6 and TNF.

How many of your patients present with one or more of these problems? Or maybe we should think of how many don’t have any of them. The point is that Glucose/Insulin related disorders are one of the most pervasive paradigms that underlie ill health in America.

Syndrome X

 Syndrome X is one of the most prominent topics in health care simply because so many Americans have it – more than 50 million and climbing. Syndrome X is a group of symptoms related to insulin resistance, officially defined by JAMA in 2002 when at least three of the following criteria present:

- Blood pressure of 135/85 mm Hg. or greater.
- Fasting serum glucose of 110mg/dl or higher (based on out of range, flagged value.)


The Journal of Hepatology also includes elevated microalbuminurea, an early warning indicator for compromised kidney integrity.

Hyperinsulinemia Defined

A glucose/insulin ratio < 4.5 to 1 is consistent with hyperinsulinemia. Legro RS et al., J Clin Endocrinol Metab 1998;83:2694).

An example using lab results would be glucose of 99 and insulin of 22 – both results are within the reference range, yet we have an abnormal phenomenon by definition and we see consistently that insulin levels lower than 22 correlate with ill health. We’ll stick with our optimal insulin value of < 10 and project a good glucose to insulin ratio in the neighborhood of 14 to 1. (Ex. 85 glucose and 6 insulin).

Cardiovascular Issues

Elevated Triglycerides

If the quantity of carbs consumed is greater than can be immediately used for energy or stored as glycogen, the excess is rapidly converted to triglycerides and stored as adipose tissue. Guyton’ Physiology 9th ed.– p.869 -870

Leptin is a hormone produced by fat cells and is involved in weight regulation by signaling the brain when fat cells are full. Triglycerides impair transport of leptins across the blood brain barrier. Short term fasting reduces triglycerides and increases transport. Diabetes 53 1253-1260, 2004 William Banks, et al.
Elevated Cholesterol
The combination of hyperinsulinaemia and hyperglycaemia produced the greatest increase in cholesterol synthesis (+51.4%, p < 0.05), but this increase was not significantly different from hyperinsulinaemia alone.

Hypertension
Elevated insulin is related to hypertension and reduced levels of nitric oxide, which relaxes blood vessels.
“Insulin resistance and vascular function.” Baron AD. J Diabetes Complications 2002 Jan- Feb;16

Rats received a high sugar diet for at least two weeks and showed significant decreases in urinary volume, creatinine and sodium with a marked increase in systolic blood pressure above baseline. After one month urinary parameters returned to baseline but the blood pressure remained elevated.

Hyperinsulinism makes sympathetic nervous system dominant - release of catecholamines, i.e., dopamine, epinephrine, and norepinephrine, which contribute to hypertension by diminishing blood vessel diameter.
Gerald Reaven, The Father of Syndrome X. Professor Emeritus (Active) of Medicine at Stanford University. (from an interview with nutritionist Robert Crayhon, M.S.).

Atherosclerosis
Elevated insulin predisposes for carotid artery atherosclerosis.

Hyperinsulinemia is an independent CVD Risk Factor

According to the Quebec study, levels of Apolipoprotein B and fasting insulin are excellent predictors of Ischemic Heart Disease (IHD).“Fasting insulin, apolipoprotein B levels and low-density lipoprotein particle size are risk factors for ischemic heart disease.” Lamarche B, Tchernof A, Mauriege P, Cantin B, Dagenais GR, Lupien PJ, Despres JP. JAMA 1998 Jun 24;279(24):1955-6

Insulin produces macrophage conversion into foam cells. A key step in the development of atherosclerosis is the deposition of cholesterol ester-filled macrophage foam cells, which contribute to the formation of atherosclerotic plaques.
Ron Rosedale, M.D.
Insulin and It's Metabolic Effects
Presented at Designs for Health Institute’s BoulderFest August 1999 Seminar

NOTE: One of the diabetic complications impacting the cardiovascular system is glycation of collagen and other vessel-wall proteins and lipoproteins.

The Official Word
Cardiovascular disease is the primary cause of death in people with diabetes, accounting for roughly 65% of mortality. Of note, increased cardiovascular risk actually precedes the formal diagnosis of type 2 diabetes by many years. In other words, the clock starts ticking years before the onset of clinical diabetes.
The Metabolic Syndrome Aaron I. Vinik, MD, PhD, FCP, FACP

Connective Tissue Damage
In diabetic patients, collagen fructoselysine, the initial glycation product, was increased threefold compared with nondiabetic subjects, correlating strongly with glycated hemoglobin but not with
age. These results support the description of diabetes as a disease characterized by accelerated chemical aging of long-lived tissue proteins.


**NOTE:** H A1c is also product of glycation. These glycation end products are somewhat like a plastic lawn chair that has been sitting in the sun for a few years. The plastic is no longer flexible and is now brittle.

**PCOS**

Polycystic ovary disease is also associated with insulin resistance


Women with PCOS are profoundly insulin resistant. This study on PCOS women found that 95% had significant insulin sensitivity as reflected by the glucose/insulin ratio of 4.5 to 1. Therapeutic courses addressing hyperinsulinemia are thought to be concurrently positive for PCOS.


**Immune Dysfunction**

Immune system impacted by glucose levels - decreased phagocytic activity of leukocytes is seen with elevated serum glucose.


**NOTE:** Although fasting glucose values are often normal, the average amount of glucose as seen in H A1c is elevated.

**Fatty Liver Disease**

Nonalcoholic steatotic hepatitis (NASH), the most prevalent form of progressive liver disease in the United States, is considered to be a manifestation of insulin resistance syndrome. In the United States, it is estimated that over 30 million adults have NAFLD. Of these, 8.6 million may have NASH. In a study of 105 obese patients (BMI over 35), independent predictors of fibrosis were hypertension (140/90 or above), an elevated index of insulin resistance, and a serum ALT level over 40.

As fatty liver disease progresses, fibrosis follows and creates scarring. Cirrhosis is the outcome of continued growth of connective tissue and is not reversible.

Nonalcoholic fatty liver disease: relationship to insulin sensitivity and oxidative stress. Treatment approaches using vitamin E, magnesium, and betaine - Fatty Liver

Alternative Medicine Review, August, 2002 by Lyn Patrick

**So Why Don’t We Just Eat Less Sugar?**

**Carbohydrate Addiction**

Rats fed excessive amounts of sugar developed an opioid-like dependence, with withdrawal symptoms similar to withdrawal from morphine or nicotine.


**How About Some Artificial Sweeteners?**

Saccharin (through taste) appears to elicit parasympathetic (insulin release) and sympathetic (hepatic glucose production increase) reflexes in lean and obese rats.


**Comment:** Insulin release starts with taste and when no glucose reaches the gut and bloodstream, a drop in blood sugar surely ensues from the already released insulin, triggering hunger to offset the resulting deficit.
Drink More Diet Soda, Gain More Weight
For diet soft-drink drinkers, the risk of becoming overweight or obese was:
- 36.5% for up to 1/2 can each day
- 37.5% for 1/2 to one can each day
- 54.5% for 1 to 2 cans each day
- 57.1% for more than 2 cans each day.

For regular soft-drink drinkers, the risk of becoming overweight or obese was:
- 26% for up to 1/2 can each day
- 30.4% for 1/2 to one can each day
- 32.8% for 1 to 2 cans each day
- 47.2% for more than 2 cans each day.

Fowler, S.P. 65th Annual Scientific Sessions, American Diabetes Association, San Diego, June 10-14, 2005

Comment: If you want to lose weight, you’re better off with sugar than artificial sweeteners!

The Stevia Question
The combination of stevioside and soy supplementation appears to possess the potential as effective treatment of a number of the characteristic features of the metabolic syndrome, that is, hyperglycemia, hypertension, and dyslipidemia. Stevioside exerts beneficial effects in type 2 diabetic Zucker diabetic fatty rats. We did not detect any effect on insulin or glucagon responses.

Metabolism. 2005 Sep;54(9):1181-8.

Comment: It appears that stevia is a viable alternative to artificial sweeteners and sugar without negative side effects. More information is needed, but stevia is a natural substance rather than artificial.

Insulin/Syndrome X Related Nutrients

Food Choices
Above ground vegetables, organic when possible, tend to be good sources of fiber and low in carbohydrates. Below ground vegetables tend to be starchy and high in carbs.

Use this glycemic index tool to select the right types of carbohydrates. High glycemic foods metabolize to glucose faster and produce undesirable effects. David Mendoza’s website is an impressive source of information on the impact of various foods on glucose. http://www.mendosa.com/gilists.htm

Vitamin C
Buffered Vitamin C – 1000 mg.+ WBC’s need vitamin C to support phagocytes whose function is diminished by excess glucose. Reducing agent.

NIH is sponsoring a new study to determine Vitamin C’s role Type 2 diabetes.

PPAR Activation - Peroxisome proliferator-activated receptors
PPAR- gamma assists fat burning – break fats into smaller chains. They are blocked by insulin! PPAR activators have been shown to inhibit the production of proinflammatory cytokines (i.e TNF, IL-6) in macrophages or vascular smooth muscle cells. Circulation Research. 2000;87:596

DHEA, Lipoic acid, Omega 3 FA, Vitamin E, CLA and Garlic activate PPAR’s.

Garlic
Garlic - Up-regulates PPAR’s, increases nitric oxide, inhibits platelet aggregation and increases fibrinolytic properties.

DHEA
DHEA – 5-10 mg. activates PPAR and inhibits TNF in monocytes.

Cinnamon
A human study published in Diabetes Care looked at 60 people with type 2 diabetes. They were divided into 6 groups: groups 1, 2, and 3 consumed 1, 3, or 6 g of cinnamon daily, respectively, and groups 4, 5, and 6 were given placebo capsules.
After 40 days, all three levels of cinnamon intake reduced fasting blood glucose ranging from 18 to 29%, triglycerides 23 to 30%, LDL cholesterol 7 to 27%, and total cholesterol 12-26%.
**Fatty Acids**  
Omega 6 and Omega 3 EFAs compete for the delta-5 and delta-6 desaturase enzymes. The combination of high omega-6 EFA intake, typical Western diet, with competition for desaturase enzyme sites in hyperinsulinism, is thus a potent stimulus to inflammation. *Insulin Resistance, Obesity And Diabetes: The Connection", Journal of Australian College of Nutritional & Environmental Medicine Vol 18 No. 1; April 1999: pages 3-10  

**Magnesium**  
Magnesium – 200 - 500 mg. Magnesium increases the rate of production of the free-radical quenching enzyme superoxide dismutase. Depletion of magnesium from normal cells creates cellular insulin resistance.  

**Vanadium**  
Vanadium – 25 mcg. An insulin mimic that works through a different mechanism to lower glucose. Improves insulin sensitivity.  

**Zinc**  
Zinc – 15-30 mg. Assists in insulin binding and is necessary for synthesis of insulin & insulinase. The zinc taste test is an easy, inexpensive way to assess.  

**L-Carnitine**  
When we lose the ability to utilize glucose and reduce carbohydrates, the need to burn fat efficiently becomes even more critical. L-Carnitine assists fats in getting into cells to combust. carnitine palmitoyltransferase I is the enzyme required for the transport of fatty acyl-CoA’s into the mitochondria where they are subject to oxidation for energy production. 200 mg. dose per day.  

**Vitamin E**  
Vitamin E – 400 IU – reduces oxidized cholesterol which is sticky and adheres to arterial wall more readily. Needed for oxidative stress related to fatty liver (NASH). Vitamin E supplementation (600 IU/day for four weeks) has also been able to significantly raise erythrocyte magnesium levels and plasma reduced glutathione levels while increasing insulin sensitivity in hypertensives.  

**GTF Chromium**  
GTF Chromium – 200 – 1,000 mcg. (Glucose Tolerance Factor) Potentiates the action of insulin at the cellular level. Positive benefits for glucose, insulin, cholesterol, HDL, triglycerides.  

**B Complex**  
Natural B complex – cofactors involved in carbohydrate metabolism, particularly biotin, niacin and thiamin.  

**Gymnema**  
The gymnemic acid is made up of molecules whose atom arrangement is similar to that of glucose molecules. Those molecules fill the receptor locations on the taste buds for a period of one to two hours, thereby preventing the taste buds from being activated by any sugar molecules present in the food. Similarly, the glucose-like molecules in the gymnemic acid fill the receptor locations in the absorptive external layers of the intestine, thereby preventing the intestine from absorbing the sugar molecules.  

Plasma glucose was lower by 18% in the Gymnema-treated animals compared to controls. The plasma glucose increase following an oral glucose tolerance test was almost normalised in the Gymnema-treated group without any alteration in serum insulin levels. Hypertriglyceridaemia, but not hypercholesterolaemia, was also improved in the treated group. *Gymnema: a key herb in the management of diabetes - Phytotherapy Review & Commentary Townsend Letter for Doctors and Patients, Dec, 2002* by Kerry Bone  

**Alcoholic Beverages**  
Consumption of 30 g/d of alcohol (2 drinks per day) has beneficial effects on insulin and triglyceride concentrations and insulin sensitivity in nondiabetic postmenopausal women. *JAMA. 2002;287:2559-2562.*  
**We suspect a positive benefit exits for most – moderation is key.**
Some Good News
There are many formulas from quality companies containing a number of the appropriate nutrients for insulin resistance. Please consult your trusted product representatives.

The Extras

New Colorectal Cancer Screening Test
We have good news about screening for colorectal cancer from LabCorp. The PreGen-Plus test has been available for several years, but the cost and reliability of the test kept us from recommending it. Now, we are pleased to report, that situation has changed for the better. Pre Gen Plus is a test using a stool sample to evaluate numerous genetic markers and those markers have been upgraded to make the test 80% accurate with the cost being about $500.

In contrast, the colonoscopy is about 90% accurate with a cost of about $1500 and we say more about the invasive issues? While no test is 100% accurate, including colonoscopy, we feel the Pre Gen Plus offers a viable alternative that will increase screening for a great many people that have previously avoided colonoscopies because of cost or the nature of the test. There is even more good news – the company has a system that is very user friendly and helpful to both patient and doctor. They will send the kit to the patient and the results to us when finished. It will be available around the first of the year.

How about other cancer markers? While it is good practice the look at these markers, they are really designed to monitor the progress of a known disease, especially after therapy, and not as screening tests. So why use them? We may find elevations in a percentage of people with no other signs and this would lead to intervention before symptoms may sound the alert.

Here, once again, is a list of symptoms that should not be ignored:

These can be remembered by thinking about the word CAUTION.

Change in bowel or bladder habits.
A sore throat that does not heal.
Unusual bleeding or discharge.
Thickening or lump in breast or elsewhere.
Indigestion or difficulty in swallowing.
Obvious change in wart or mole.
Nagging cough or hoarseness.

Please do not ignore any of these symptoms that persist more than two weeks. We should always seek the cause of such symptoms and using the various cancer markers would be appropriate as part of that goal. PCS does its best to keep the cost of these tests affordable.

PCS Lecture At FCA Naples, FL
The Florida Chiropractic Association has once again given us the opportunity to present a lecture for CEU’s, this time at their annual Winter Convention in Naples, FL on Dec. 9, 2005

Disease Processes Related to Sub-Clinical Glucose and Insulin Excess with Hormonal Relationships and Laboratory Assessment

The Underlying Link to Ill Health in America

Persistent, moderately increased levels of glucose in the American population have become a significant and insidious link to chronic degenerative diseases. A myriad of disease entities (including Syndrome X, diabetes, cardiovascular disease, hypertension, fatty liver (NASH), chronic inflammation, acidic metabolism, cancer and others) can all be related to impaired glucose metabolism. Added relevance of hormonal imbalances/influences makes this lecture a powerful bridge to clinical success in connecting to the underlying issues of many of today’s most common health problems. Physiology, pathology and biochemistry are
presented in detail along with laboratory assessment and therapy considerations.

Presented by:
J. William Beakey, N.M.D., Dipl. Homeopathy
Professional Co-op Services, Inc.

We plan to have available the notes and audio of this lecture topic for a nominal fee.

Hormones
There is no shortage of hormonal issues intertwined with insulin resistance. Cortisol, thyroid hormones, DHEA, Vitamin D, testosterone and leptins are all impacted negatively.
For more information on hormones and iodine, see www.drbrownstein.com the website of Dr. David Brownstein, MD, one of our leading holistic clinicians who has authored several easy to read and very understandable books on hormones and iodine. His new book on SALT is now available. Dr. Brownstein presented seminars on hormones from Professional Co-op and the feedback has been excellent. If you are interested, he will be lecturing in Greensboro, NC on October 15, 2005. Call us for contact information. PCS will keep you posted on his future lectures.

New Ranges for Vitamin D
We are pleased to report that LabCorp has recently adopted new classifications for vitamin D status based on an article in the British Journal of Nutrition by A. Zitterman “Are We Ignoring the Evidence?”

Deficiency – 0-5 ng/ml
Insufficiency – 5-20 ng/ml
Hypovitaminosis – 20-40 ng/ml
Sufficiency – 40-100 ng/ml
Toxicity - >100 ng/ml

Let the sunshine in – literally and figuratively.

Low On Collagen? Try This Recipe

Collagen-Rich Soup Stock Recipe
4 pounds organic chicken carcasses, including necks and backs
1 large onion, quartered
4 carrots, peeled and cut in 1/2
4 ribs celery, cut in 1/2
1 leek, white part only, cut in 1/2 lengthwise
10 sprigs fresh thyme
10 sprigs fresh parsley with stems
2 bay leaves
8 to 10 peppercorns
2 whole cloves garlic, peeled
2 gallons cold water

Place chicken, vegetables, and herbs and spices in 12-quart stockpot. Set opened steamer basket directly on ingredients in pot and pour over water. Cook on high heat until you begin to see bubbles break through the surface of the liquid. Turn heat down to medium low so that stock maintains low, gentle simmer. Skim the scum from the stock with a spoon or fine mesh strainer every 10 to 15 minutes for the first hour of cooking and twice each hour for the next 2 hours. Add hot water as needed to keep bones and vegetables submerged. Simmer uncovered for 6 to 8 hours.

Strain stock through a fine mesh strainer into another large stockpot or heatproof container discarding the solids. Cool immediately in large cooler of ice or a sink full of ice water to below 40 degrees. Place in refrigerator overnight. Remove solidified fat from surface of liquid and store in container with lid in refrigerator for 2 to 3 days or in freezer for up to 3 months. Prior to use, bring to boil for 2 minutes. Use as a base for soups and sauces.

Our New System at PCS
You have been receiving packets from PCS with new HIPAA agreements, price lists and new instructions with sample forms for requisitions. Please be sure you have mailed back your forms. We believe the new system will be easier and more professional. Please keep in mind that filing your paperwork is critical to the process and the only way our office can keep track of 400 doctors. Thank you for your co-operation and understanding.
Next Topic: Vitamin D
A hot topic with lot’s of implications that we can assess and deal with successfully!

Your comments and suggestions are welcome.

Thank you!

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FDA has not commented on the above-mentioned studies or statements

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