GCCM

August 11, 2000

Ms. Patricia Holobaugh
Division of Inspections and Surveillance
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852

Dear Ms. Holobaugh:

As you requested in our phone conversation of 8-8-00, I am enclosing a list of our IRB projects according to whether they are under be FDA jurisdiction, and whether they require an IND/IDE as best we can tell.

A. Projects not under the FDA jurisdictin:

*Henry Heimlich, MD S074 Heimlich Maneuver for Asthma

*Russell Jaffe, MD S058 Determining the Role of Food/Environment Sensitivities in Patients with Diabetes.

*D Musnick, MD, D. Klinghardt MD, S068 Low Level Laser for Treatment of Acute and Chronic Muscular-Skeletal Pain and Neurologic Symptoms.

*Lawrence Young, MD S076A Gentle Physical Exercise, Breathing and Visualization as the Acupuncture Device.

B. Projects for which we have conflicting information from FDA sources as to whether and IND is required because they are off label uses for approved medications:

*Alfredo Lopez del Castilla, MD S060 Reconstruction Therapy for Intractable Low Back Pain.

*Paula Bickle, PhD S081 A protocol for Studying Mobilization of Mercury by Giving DMPS Orally to Humans.

*Jack Hinkle, DO S066 Chelation Therapy for Arteriosclerotic Disease.

*Jack Hinkle, DO S067 Chelation Therapy for removal of Heavy Metals (specifically Mercury) after DMPS Injection

*L Terry Chappell, MD M021 EDTA Chelation & Coronary Artery Disease Patient Registry

C. Projects that definitely need and IND and the chief investigator is already working with the FDA to get the IND:
*Roy Page. MD & George Kindness, MD M029 Adjuvant Immune Therapy in the treatment of Solid Tumors Through Modulation of Signaling Pathways Following Engagement of Humoral and Cell Mediated Responses.

*W.A. Shrader, MD M026 Evaluation of the Effect of the Immunotherapeutic Techniqus Enzyme Potentiated Desensitization (EPD) for a Considerable Variety of Illness/Conditions/Diagnostic Conditions.

D. Projects that may need and IDE:

*William Kubitschek DO Gerlinde Moll S055 Treatment of Sports Injuries with the/IBX Inductive Bio-Stimulation Therapy

E. Projects that are inactive, completed, moved or have been terminated.

Project is completed. Constantine Kotsanis S069 Intravenou Secretin to Effect Positive Behavior Changes in Autistic Individuals.

Moved to another IRB due to FDA hold. Warren Levin, MD S084 Effects of Growth Hormone (GH) or Growth Hormone Releasing Hormone (GRF) on Age-Related Insulin Resistance, Pulmonary Function and Quality of Life.

Terminated due to lack of response:

William Maner, DO S004 Phototherapy as a Modality In The Stimulation of the Immune System.

Lawrence Porter, MD S049 Chelation Therapy for Arteriosclerotic Disease (using GLCCM protocol)

Paula Bickle PhD, S081 A Protocol for Studying Mobilization of Mercury by Giving DMPS Orally to Humans.

Inactivated due to FDA restrictions:

*George Kittiness, MD & Timothy Guilford MD S082 Use of EDTA (Extreme Dilution) Therapy for Allergy.

*Kent Pomeroy, MD M023 Pain Alliviation & Joint Functino Improvement by Prolotherapy

*Bill Wesendorf, DDS M010 Amalgam Removal and Mercury Detox

*Steven Ayre, MD M064 Insulin Potentiation Therapy

*Cary Moore, MD S077 Ca-EAP Therapy as an Adjunct in the Therapy of Patients with Multiple Sclerosis.

For projects in category B, we are requiring that the investigators get written statements from the FDA as to whether they need an IND.

We understand from our phone conversation, that this letter will lift the "hold" you have placed us under while we continue to work out the changes you requested in your latest letter and that your web site will reflect this change in our status.

You explained to me that you are not trying to shut down our IRB and that this letter would enable us to function fully while we continue to work to satisfy the various revisions you have asked us to make during your last 3 letters to our IRB.

Sincerely,

Jack Hank
Executive Director