APOSTOLIC SCHOOL OF NATURAL MEDICINE

Clinical Study Nº 716/03
Pathology: Diabetes-2

Preparation: Milagro de la Selva™ tea

Manufacturer: Milagro De la Selva, S.A. Guatemala

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Study begin: 03-01-03 Study conclusion: 05-31-03

APOSTOLIC SCHOOL OF NATURAL MEDICINE

STUDY 0716/03
PREPARATION: Milagro de la Selva™ tea

Ambulatory Naturopathic Treatment of Diabetes-2

The Rationale of Milagro De La Selva Tea

The ultimate fuel utilized by each of the 30 to 40 odd trillion cells that make up the average human body is glucose, which is the purest form of sugar. In other words, all cells are equipped to convert sugar into the raw energy they require or their functions. Thus, sugars represent the very source for the perpetuation of life.

There are many forms of sugar in Nature – commonly known as carbohydrates – that serve as nourishment for humans. Dextrose is one of the simple sugars found in many foods and constitutes the major source of energy for the human cells. However, the human organism was designed by Nature to synthesize glucose from manifold nutritional sources, such as proteins for example. What is important to know is that regardless of when eaten or produced in the body, sugars are transferred into the blood from the intestinal tract. In a healthy body, excess glucose in circulation is stored in the liver and muscles as glycogen, and is converted to glucose on demand, and released as needed.

The human organism is endowed with sophisticated equipment that constantly measures the blood's glucose levels and continually reports the data to those thalamic and hypothalamic sectors in the brain, which are tasking the metabolic mechanisms.

Metabolism is the term that describes the sum of all chemical processes, which take place in the body. There are two main categories of metabolism: the

build-up, known as anabolism; and the break-down, known as catabolism. In anabolism, smaller molecules such as amino acids are put together – *synthesized* – into larger molecules, such as proteins. In catabolism the opposite is true**.** Larger molecules, like glycogen, are broken down into smaller molecules, such as glucose. The hormone insulin serves as the catalyst for the catabolic process. Insulin is manufactured in the pancreas and requires the mineral zinc for its production. Several nutrients are extremely important in the glucose metabolic process, such as Vitamin B1, Niacin, and Iodine.

Public notion regarding Diabetes unvaryingly associates the condition with the pancreas. Now, while this is quite correct, in order to rationally interpret the disease, it is of paramount importance to consider the liver as well. It is well known that the liver is a “multi-tasking” organ, meaning that it simultaneously carries out several tasks.

Most every one has a working notion about the different obligations of the liver. However, it is not generally known by the public, that the prime responsibility of the liver is sugar administration. Thus, when the pancreas fails to produce sufficient insulin – the hormone that regulates the sugar levels in the blood, – the liver begins to malfunction because it becomes overwhelmed by the sugar excess and Diabetes-2 evolves. This type of diabetes usually arises in the latter ages of individuals prone to this disease. In some cases, the subdued hepatic mechanisms send erroneous signal to the immune system, causing diabetics develop resistance to insulin, which – since in this case pharmaceutically administered insulin does become useless – aggravates the prognosis.

Juvenile Diabetes, classified as Diabetes-1, is genetically inherited, thus develop at much earlier ages, in some cases even in childhood. These cases are even more taxing to control, because the disorder evolves following chromosome

mechanisms similar to those that determine our skin, eye and hair color. In other words, the individual is born with the condition.

In brief, conventional medicine has, to this date, not yet developed any universal cure for diabetes. Milder cases can be controlled through diet and hypoglycemiant agents; whereas advanced cases require perpetual insulin injections around the clock. As we have already mentioned, the patients with the poorest prognosis are those who developed resistance to insulin.

There are numerous food supplements on the market, offering alternative, drugless methods for diabetes control. While it is undeniable that they are obviously preferable to drugs, also these have to be taken perpetually, let alone the fact that in most insulin-dependent cases such food supplements can only reduce the hormone requirement at best.

Nonetheless, help became available from completely unexpected quarters. Alberto Ruiz, a graduate Guatemalan naturopathic physician – who started his career as an agricultural engineer trained in U.S. Universities – became fascinated with ancient Mayan medicines, based on herbs that grow in the lush rain forests of Guatemala and the Southern territories of Mexico, where up to twelve hundred years ago the legendary Mayan Empire thrived.

The Mayan culture left a stunning legacy behind when it vanished virtually overnight towards the end of the ninth century AD, about six-hundred years before the Spanish conquest began. Regrettably, the fanatic horde of Spanish idol-smashers systematically destroyed every vestige of written records of the Maya.[1] Only pieces carved in stone survived the devastation wrought by the

[1] Only the Codices survived the devastation carried out by the Spanish priesthood, which were eventually taken to Europe by the Spanish overlords who snatched them out of the monks' hands and kept them as souvenirs. Much later, in 1951; an archeological team working in Palenque, State of Chiapas, which used to be the Northern portion of the Mayan Empire, discovered a fourth

Conquistadores, in consequence until very recently it was impossible to translate the few still existing Codices.

Thus, most of the extant fragments of this phenomenal culture survived by being passed on from fathers to sons, generation after generation, along the centuries. It was through such a roundabout course that ancient Mayan medical information could stay alive and transcend into the present. Indigenous medicine men – called *shamans* – were, and continue to be practitioners of this ancient, yet unvaryingly valuable knowledge.

It was by sheer chance that Ruiz became aware of the existence of this archaic erudition and, being an agronomist by training, began a disciplined, systematical study of the herbs growing in the rain forest.

One of the facts that called his attention was that diabetes is an almost unknown malady among the indigenous that populate these rain forests. He carried out an in-depth investigation of the phenomenon and discovered that the natives drank a tea made by combining three different herbs, as part of their daily liquid source. Dr. Ruiz decided to research the obvious medicinal effects of these three native herbs.

The two plants are SMILAX DOMINGENSIS AND TECOMA STANS. Eventually he discovered that these herbs, when properly processed, do combine synergistically, thus effectively amend both the pancreas and liver, repairing and modulating their functions. The concept of s*ynergism* asserts the blending of specific components in a formula, which are not only perfectly compatible with each other, but do interact as well in a manner that enhances the purpose of both the individual components the finished supplement that they

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Codex, which the natives have hidden in a cave when the Spaniards began to perform their general culturicide.

integrate. Continuing his research, Dr. Ruiz developed a proprietary technique of processing the plants incorporated in the tea, that he named *Milagro de la Selva*, which enhances and ensures the effects of his product.

In due time, Dr. Ruiz verified the effects of the tea by treating 40 volunteers of both sexes, afflicted with Diabetes-2. The tea brewed with the processed herbal combination effectively normalized the glucose blood levels of the participating volunteers. He ran the test for six months and established that 24 – 60% – of the patients was able to interrupt the treatment with normal and stable glucose levels. The remnant 16 patients had to resort to the tea again after two weeks of interruption.

Appropriate, officially carried out tests established that the tea is non-toxic, hypoallergenic and is completely void of any side effects.

After carrying out appropriate Studies at Universities in Guatemala and Costa Rica, Dr. Ruiz obtained registration of the tea from the Guatemalan Department of Health, and began the marketing of the product.

Ongoing Studies have also proven that the tea benefits vascular problems of the retina, which is a concurrent condition of many diabetics. New studies will address the possible therapeutic effects of the tea in Diabetes-1, which hitherto resisted all kinds of treatment other than insulin.

Nature required millions of years to evolve us as we are at present. Yet our evolution did not incorporate refined sugar in our nourishment. We were designed to convert proteins and, to a much lesser extent, simpler carbohydrates into sugar that fuels our trillions of cells. Notwithstanding, the eating habits of our contemporary Society is virtually plagued by sugar. Refined sugar appeared in our diet a mere couple of centuries ago. A hundred and fifty years ago the average metropolitan citizen consumed yearly about three to four pound of

sugar. At present the same citizen consumes – including sweetened foods, soft drinks, sugar used as preservatives and desserts – about yearly two hundred pounds of refined sugar. In other words, we recklessly attempt to modify our biological gear in but a few generations from the original design that took Nature millions of years to evolve. Needless to say we are running a collision course with catastrophe. In flagrant contradiction to the school, which maintains that acquired biological modifications cannot be transferred genetically from one generation to the next one, diabetes is escalating epidemically. Let alone the fact that the pandemic escalation of obesity is, far more than fat, caused also by our excess of sugar intake. The effects of the tea reveal that the sugar excess in the body rather than being stored in the body after having been removed from our blood stream is being discarded with our biological waste.

New Studies are carried out to reveal if the tea could perhaps be useful in the prevention of the fatal consequences of the excessive sugar in our daily nourishment. Time will tell.

Note: The tea is manufactured in Guatemala and legally imported into the USA.

PEOPLES UNIVERSITY OF THE AMERICAS
HOLY ORTHODOX CHRISTIAN CHURCH
Patriarchate Of. Puerto Rico

ASSAY PERFORMED ACCORDINGLY TO GUIDELINES SET BY A.O.A.C.

PRODUCT: **Milagro de la Selva Phytotherapeutic tea** MANUFACTURER: Milagro De La Selva, Inc., Guatemala Batch: 191/03 Date: 03-24-03 Reference: 1229/03

SPECIMEN DESCRIPTION: rough surfaced, considerably porous brown, dehydrated young tree barks, presented in hermetically sealed, chemically inert plastic containers.
TEMPERATURE: Measured at 63°F
RELATIVE AMBIENT HUMIDITY: 48%
NOTE: 100 gm net test material was used in the determinations.
FINDINGS: The test material was fermented and processed conforming to the Manufacturer's proprietary process, not disclosed here. For further information contact the Manufacturer.

ASSAY:

SMILAX DOMINGENSIS fermented bark	45 g
TECOMA STANS fermented bark	55 g

	Total	100 g

CONTAMINANTS	
PCB	Less than 1 PPM in 100 gm
Arsenic	Less than 1 PPM in 100 gm
Lead	Less than 1 PPM in 100 gm
Other heavy metals	Less than 1 PPM in 100 gm
Salmonella	Negative in 100 gm
Entero-amoeba Coli	Negative in 100 gm
Other coli-forms	Negative in 100 gm
Pesticide residues	Gas chromatography reads negative for both chlorinated and organophosphate pesticides and insecticides.

Product: Milagro de la Selva tea	Assay # 1229-03	Page 2

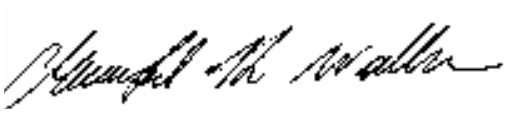
PSYCHOMOTOR or NEUROGENIC DRUGS:	No existing variety was detected
ANTIBIOTICS:	No existing variety was detected
HORMONES:	No existing variety was detected

METHODS USED: All determinations were carried out according to guidelines described in the 2001 Edition of Official Analytical Methods, published by A.O.A.C. on file with the Federal Register. JOAC 68 677(1985); 69 259(1986); Titrimetric Methods: JAOAC 18 140, 19 373, 21 97(1938); CA8-9001-73-4; JAOAC 54 978 (1971) (as chromatography). Plus standard phase- and dark field microscopy was used.

OBSERVATIONS:

- No binder or filler substances, such as gluten, starches or sugar were found in the tested material, above identified as Milagro de la Selva tea.
- The fermentation and blending processes are proprietary information. For pertinent inquiries contact the manufacturer

REPORTING CHEMIST: Manfed K. Wallner MS, NMD member of A.O.A.C.



PEOPLES UNIVERSITY OF THE AMERICAS
HOLY ORTHODOX CHRISTIAN CHURCH
Patriarchate Of. Puerto Rico

LA TOUR A.C.

Sociedad Internacional de Gerontologia

Valparaíso 424, Tlanepantla, Edo.Mex. 53020
Tel. (52-555) 370-6889

CLINICAL RESEARCH DIVISION

LETHAL DOSE – *LD50* – DETERMINATION
Product: MILAGRO DE LA SELVA Tea.

Customer ID:	1292-02-E-02		
Manufacturer:	Milagro De La Selva, S.A., Guatemala		
Product:	Milagro De La Selva Tea		
Formula:	Each 100 g contains:		
	SMILAX DOMINGENSIS shredded bark 45 g		
	TECOMA STANS shredded bark 55 g		
Protocol:	**Daily doses**: The beginning daily dose was 32ml of the test material, the equivalent to 4X the recommended daily dose for humans, determined at 8ml/kg weight. The daily doses were progressively increased every 5th day with additional 4ml test material to the 25th day. Thus, during the last five days of the test period all test animals received 6X the recommended daily doses for humans **Method of administration**: progressive, by natural feeding. The test doses plus 5% for spillage was added to the animals' standard daily nourishment.		
Duration:	30 consecutive days		
Date of test begin:	01-21-03	**Date of test conclusion:**	02-22-03
Animals used: **Population:**			
Test report:	90-day old, laboratory-certified healthy, non-vaccinated Norwegian black rats of average 200gm weight. 50 labeled (25 males + 25 females) animals without control group. **Note:** The animals were housed in five shared, decontaminated cages with ten in each. **None of the animals died during the test period. All**		

	animals developed loose stool 48 hours after beginning the test, which gradually escalated to mild diarrheic stools throughout the test period. Their behavior and appetite remained unaffected. Their vital signs remained perfectly stable during the entire test period. The diarrheic stool abated 48 hors after the administration of the last dose. In spite of the diarrheic stool their average weight gain was 6 the expected 6%.
Observations:	1. The average weight gain of healthy animals of this species is approximately 6% in their fourth month of life. 2. The vital signs of all test animals were controlled every fifth day 3. None of the animals was sacrificed at the end of the test. The protocol called for autopsy only on animals that died in the course of the test.

Tlanepantla, Edo.Mex. 02-26-03

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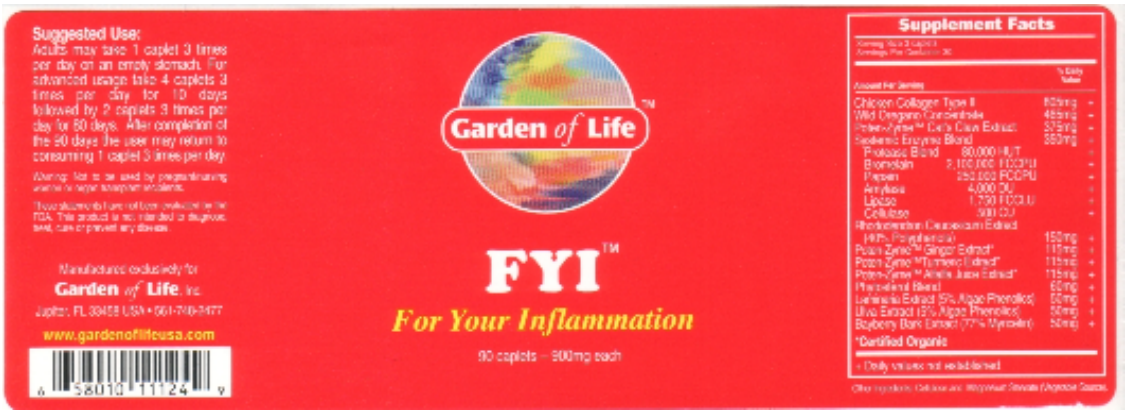
Lidia Rangel MD
Director of Research

English version



Paste original Product label here

APOSTOLIC SCHOOL OF NATURAL MEDICINE

STUDY ABSTRACT Nº 0716/03 PREPARATION: Milagro de la Selva™ tea

Ambulatory Naturopathic Treatment for Diabetes-2

INCLUSION CRITERIA:

- Individuals of both sexes suffering from clinically confirmed **Diabetes-2,** who have shown to be resistant to conventional forms of medications. All selected patients are suffering from chronic diabetic symptoms.
- Both sexes of ages between 45 and 70 years.
- Individuals who have not been treated with tranquilizers, anti-depressants, steroids and/or chemotherapeutic drugs for at least 3 months prior to the beginning of the study.
- Individuals who have not received any prescription medicines other than Insulins and/or oral hypo-glucosants for at least 3 months.

EXCLUSION CRITERIA:

- Individuals declared in critical condition by a licensed health practitioner.
- Individuals afflicted with any acute infectious disease, cardio-vascular, renal or immediate life-threatening pathologies.
- Individuals who have received surgical replacement or any of their joints or organs.
- Allergies to any of the components of the Milagro de la Selva™ formula.
- Individuals who have been subjected to tranquilizers, antidepressant, chemotherapeutic or steroid drugs less than 3 months prior to the beginning of this study.
- Alcoholics and/or drug addicts.
- Convalescents of any trauma more recent than 3 months.
- Individuals receiving life-supporting prescription medications, which affect the immune and/or nervous system (Such as certain hormones other than Insulins and/or hypo-glucosants, tranquilizers or anticonvulsive drugs).

APOSTOLIC SCHOOL OF NATURAL MEDICINE

Clinical Study Nº 0716/03 Preparation: **Milagro de la Selva™** tea

STUDY PROTOCOL

1. All participants undergo physical and laboratory examinations prior to the beginning of the Study.
2. The Study is carried out under a standard, ambulatory, simple-blind regime.
3. Test treatments must begin not later than 15 days after the completion of the above laboratory tests and physical examination.
4. The test material consists of daily oral doses of 5g of **Milagro de la Selva tea™** (see attached assay) prepared in one (1) liter of distilled water or purified by reverse osmosis. The daily dosage is taken in fractionated doses throughout the day for a 90-day period.
5. During the entire course of the Study, the participants will abstain from consuming both prescription and/or OTC drugs, unless it becomes inevitable, in which case that particular individual will become disqualified from the study.
6. All participants of the study will be supplied with test material sufficient for 10-day periods. All participants must collect fresh supplies in person every 10 days, at which time they will report their subjective findings to the health practitioner in charge.
7. The study target consists in determining the palliative or attenuating effects of the herein identified test material in human adults of both sexes afflicted with **Diabetes-2.**
8. At evaluating the final test results, both curative and attenuating effects shall be defined by the following gradation: full remission = A; partial remission (symptom palliation with objective proof) = B; moderate palliation = C; unchanged condition = D; worsened condition = E.
9. The Study population will consist of 35 human male and female adults from 50 to 70 years of age, receiving test material, plus an equal group of control individuals receiving placebo; both groups do conform to parameters specified by the Inclusion Criteria.
10. The duration of the study will be of 90 days.
11. Glucose and lipid controls will be carried out every 30 days and 15 days after completing 90 days of administration of the test, respectively placebo material. At the conclusion of the test, all patients will again undergo complete physical examination.

12. All Study participants must sign their willingness to partake in this study and their conformity to the rules and regulations of this protocol, prior to the beginning of this Study.
13. Any deviation from the above rules will disqualify the participant from the Study and will be written off as a dropout.
14. The Study will be carried out under the direction of a duly licensed Doctor of Medicine or of Naturopathic Medicine, assisted by qualified paramedical associates and certified laboratory technicians.
15 The Study will be carried out subordinated to the control of the Clinical Research Division of the Apostolic School of Natural Medicine of the Peoples University of the Americas, at Ponce City, Puerto Rico.
16 Considering that, conforming to the Exclusion Criteria of this study, all participating patients have shown to be resistant to conventional types of medication; the test is carried out under a standard, mono-therapeutic, regime.

Note:
Full remission signifies entirely – both objectively and subjectively – asymptomatic conditions.
Partial Remission refers to 60% or better improvement.
Moderate Palliation implies 40% improvement.

APOSTOLIC SCHOOL OF NATURAL MEDICINE

STUDY VERIFICATION

CLINICAL STUDY Nº 0716/03
PREPARATION: **Milagro de la Selva™** tea

- TYPE OF STUDY: Standard, ambulatory, mono-therapeutic, simple-blind regime, with equivalent control group
- PREPARATION USED: **Milagro de la Selva™** tea.
- INGREDIENTS: **Milagro de la Selva™** tea containing an all-natural, herein listed phyto-therapeutic formula disclosed in the attached assay, produced conforming to a proprietary manufacturing process.
- OBSERVATIONS: The herein tested preparation is being marketed since December 2001.
- MANUFACTURER: Milagro de la Selva, S.A., Guatemala.
- OBJECTIVES: Palliation or attenuation of **Diabetes-2** in both sexes.
- RATIONALE: See abstract.
- POPULATION: 35 human individuals of both sexes between ages of 50 and 70 years, with an equivalent control group.
- CRITERIA: See attached protocol.
- DOSAGE: infusion prepared with 8.2g of tea in 1 liter of pure water taken daily for 90 days, administered as mono-therapy.
- POPULATION AT CONCLUSION OF THE STUDY: not less than 30 participating voluntary patients.
- DATE OF BEGIN: 03-01-03 DATE OF CONCLUSION: 05-31-03
- DURATION: 90 DAYS.
- PROTOCOL: Attached.
- AUTHOR OF THE STUDY MODEL & PROTOCOL: Peter R. Rothschild, MD, PhD, Puerto Rico.
- DIRECTOR OF THE STUDY: Omar C. Jahen NMD.
- EVALUATION: Certified copy attached.

APOSTOLIC SCHOOL OF NATURAL MEDICINE

CERTIFIED EVALUATION OF THE CONCLUDED STUDY

TEST PATIENT GROUP

Clinical Study Nº0716/03 Preparation: **Milagro de la Selva™** tea

GRADATION

A	B	C	D	E	Dropouts	Total
21	10	3	0	0	1	35

Test group population at the beginning of the study: 35 adults.
Test group population at the conclusion of the study: 34 adults.

OBSERVATIONS:

1. All determinations were performed according to the norm guidelines set by W.H.O. for standard, ambulatory, non-invasive clinical examination methods.
2. Each patient underwent CBC, SMAC-24 laboratory determinations, carried out not more than 15 days before and 15 days after the trials.
3. Each patient underwent monthly Glucose, Total cholesterol and Triglycerides determinations between beginning and closing of the Study.

APOSTOLIC SCHOOL OF NATURAL MEDICINE

CERTIFIED EVALUATION OF THE CONCLUDED STUDY

CONTROL GROUP (PLACEBO PATIENTS)

Clinical Study Nº0716/03 - Preparation: **Milagro de la Selva™** tea

GRADATION

A	B	C	D	E	Dropouts	Total
0	0	2	14	3	16	35

Control group population at the beginning of the study: 35 adults
Control group population at the conclusion of the study:19 adults.

OBSERVATIONS:

1. All determinations were performed according to the norm guidelines set by W.H.O. for standard, ambulatory, non-invasive clinical examination methods.
2. Each patient underwent CBC, SMAC-24 laboratory determinations, carried out not more than 15 days before and 15 days after the trials.
3. Each patient underwent monthly Glucose, Total cholesterol and Triglycerides determinations between beginning and closing of the Study.

APOSTOLIC SCHOOL OF NATURAL MEDICINE

SUMMARY

Study Nº 0716/03 Preparation: **Milagro de la Selva™** tea

The end results of the Study, in general, do indicate that *Milagro de la Selva™* tea qualifies as efficient therapeutic agent for **Diabetes-2**. It is evident that the preparation does trigger palliative, and occasional curative effects in the herein indicated pathological condition

The present Study was designed on basis of appropriate laboratory tests carried out and proper physical examinations performed on each patient before and after the trial. In addition, subjective findings such as the remitting and/or disappearance of symptoms were evaluated as well. No previous pertinent statistical data was considered.

It is justified to emphasize that approximately 90% of the participating test patients achieved partial remission or better at the conclusion of the Study. Moreover, with the exception of one disqualified dropout, each or the restant 3 participants did attain varying but considerable degrees of palliation.

The placebo effects observed in the control group were virtually absent. 16 patients of the original 35 pertaining to the control group dropped out of the study because of disappointment due to total lack of palliative results.

The health practitioners in charge of the Study report that: the obtained results revealed that the **Milagro De La Selva™** tea constitutes an effective naturopathic treatment for the palliation and attenuation of **Diabetes-2** resistant to conventional forms of treatment**.**

In order to determine the possible enduring capabilities of this natural preparation, it is recommended that further tests as well as follow-up examinations of the participating patients should be carried out over more extended periods.

Summing up the results obtained, the Director in charge of this Study and his collaborating colleagues conclude that the **Milagro De La Selva™** tea contains a natural neuro-immuno-modulatory and regulatory formula that shows significant efficacy in treating **Diabetes-2**, thus definitively deserves further, in-depth investigation.

In witness thereof, the Director of the above Study signs and seals this report at Ponce, Puerto Rico, on June 19, 2003.

Director of the Study
Omar C. Jahen NMD

Extracurricular Appendix.

It is noteworthy to mention that 17 of the tested patients have reported significant further relief from additional conditions, which, due to the general modus operandi that rule Clinical Studies, cannot be incorporated in this report.

Notwithstanding, extra-official reports covering the above effects are being furnished directly to the manufacturer.