FINAL REPORT

TITLE: THE EFFECT OF REPEATED ORAL INTAKE OF TWENDEE FOR TWELVE WEEKS ON GLYCEMIC CONTROL AND INSULIN LEVELS OF MALE AND FEMALE ADULT VOLUNTEERS WITH TYPE 2 DIABETES MELLITUS

TRIAL NUMBER: NRP07-001

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(Number of pages: 18)

1	**Title:**	The Effect of Repeated Oral Intake of Twendee for Twelve Weeks on Glycemic Control and Insulin Levels of Male and Female Adult Volunteers with Type 2 Diabetes Mellitus
2	**Trial Number:**	NRP07-001
3	**Sponsor:**	Brookfield Medical Co., Ltd. 1-1-11-504 Kokumachi, Chuo-ku, Osaka-city 540-0033 JAPAN TEL +81 6-6941-5781, FAX +81 6-4793-8229
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Volunteer Management Office
1409 Old National Highway,
Bgy. Dila
City of Santa Rosa, Laguna 4026, PHILIPPINES

7 Test Material:

Generic Name:	Amino Acid Supplement
Brand Name:	Twendee
Composition:	Mixture of several kinds of amino acids
Manufacturer and Source:	Brookfield Medical Co., Ltd.
Dosage:	1.8g/ 3capsules; 3 capsules shall be taken 30-35 minutes prior to each meal

10 Trial Schedule:

Screening:	May 5, 9, and 12, 2007
Administration period:	May 22, 2007 ~ August 14, 2007

11 Trial Personnel

In-Charge of Sample Analysis:	Rachel G. TAYAMORA, R.M.T., R.Ph.
In-Charge of Standard Food and Test Material Management:	Jane G. CIPRIANO, R.M.
In-Charge of Standard Food and Test Material Administration:	Cherrie C. RUSTRIA, B.S. H.R.M.
Clinical Examiner:	Ana Marie V. ULIT, M.D.
Research Nurse:	Joan T. ROSALADA, R.N.
Statistician:	Marielle E. ORTIZ, B.S. Stat.

12 Deviations from the Protocol and Incident Report

- According to the protocol, the subjects should take their meals 30-35 minutes after Twendee intake. However, on Day 14, M07-01-A1 took lunch one hour after of taking Twendee and F07-01-A4 took dinner 2 hours and 5 minutes after taking Twendee. The delay of food intake from the prescribed time period on one occasion in both subjects was due to unavoidable circumstances reported by the volunteers (M07-01-A1 and F07-01-A4) in their food diary. The deviation was not expected to have a remarkable effect on the study evaluation parameters (GLU, Insulin, HbA1c) in this repeat oral intake food study.

- According to the protocol all unused test materials were to be returned to the Sponsor at the end of the trial. However, the sponsor made a decision to have the test materials disposed at the test site(s) instead of having it returned to them.

PREPARATION OF THE FINAL REPORT:

Principal Investigator:

	9/11/07
Ana Marie V. ULIT, M.D.	Date

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The Effect of Repeated Oral Intake of Twendee for Twelve Weeks on Glycemic Control and Insulin Levels of Male and Female Adult Volunteers with Type 2 Diabetes Mellitus

ABSTRACT

This trial was conducted to evaluate the effect of repeated oral intake of Twendee for twelve weeks on glycemic control and serum insulin levels of adult male and female volunteers with Type 2 Diabetes Mellitus.

Twelve (12) diabetic subjects (5 males and 7 females) who fulfilled the specified pre-test HbA1c and FBS values and the inclusion criteria were selected and completed the 12-week trial. The subjects were required to take three (3) capsules of Twendee 30 to 35 minutes prior to each meal (breakfast, lunch and dinner) daily.

Under fasted conditions, serum glucose and insulin measurements, and HbA1C concentration determinations were done during the pre-test and once every two (2) weeks during the study period according to the following schedule: Pre-test and, Days 15, 29, 43, 57, 71 and 85. The subjects likewise underwent medical interview and pertinent physical examination (PPE), and hematology and blood chemistry examinations during the pre-test; 3 (Day 4), 7 (Day 8) and 14 (Day 15) days and 4 weeks (Day 29) after initiation of Twendee intake; and once every four weeks thereafter (Days 57 and 85) during the study period for health monitoring.

Compliance monitoring was strictly conducted and the subjects were instructed to accomplish their Test Material and Food Records which were collected and reviewed weekly prior to issuance of the test material supply for each week.

Data were expressed as means + standard deviations (SD). The HbA1c, glucose and insulin concentration values were analyzed for the effects of the test material using analysis of variance (ANOVA). Differences at 0.05 level of significance were considered significant. The data were analyzed using the SAS statistical software package (SAS/STAT Version 9.1; SAS Institute, Cary, NC).

No Side Effect

No clinically significant change in the hematology and blood chemistry parameters were noted suggesting that Twendee can be safely administered daily to diabetic subjects at a dose of 1.8g/3 capsules 30 to 35 minutes prior to each meal (breakfast, lunch and dinner) for twelve weeks. Further studies are recommended to confirm these findings.