Pennington Biomedical IRB FWA 00006218
Approved May 14, 2020

Pilot Study Evaluating the Hedonic Acceptability and Absorption of the Bioactive Compounds of a 5011-Nutrasorb Bar (Russian Tarragon Nutrasorb)

February 12, 2020

Background: Based on previous safety studies with 5011-Nutrasorb, it was decided to develop 30g into a high fat bar that would be acceptable in taste and that would provide detectable levels of 5011 in the circulation.

Objective: 5011-Nutrasorb can be formulated into a high fat (40% kcal from fat) bar that is safe and acceptable for human consumption and is compatible with detectable serum levels of the identified bioactive compounds within 6 hours of consumption

Phase 1

Aim 1: Formulate a bar containing 30 g of 5011-Nutrasorb and 40% fat. The goal is to develop a bar containing the following:

30 g PMI 5011-Nutrasorb (120 kcal)

20 g fat (100 kcal)

Remainder kcal (30) from carbohydrate and flavorings

Total kcal of bar – 250 kcal

Aim 2: Determine by visual analog scales the acceptability of the bar.

Study Design: 10 healthy participants will be enrolled into the study. The study will have a single testing visit. Once all 10 people have completed the study, the visual analog scales will be reviewed. The study may be repeated with the same 10 participants two additional times in case the first or second product is not acceptable. If the initial bar is not acceptable, the fat source and/or flavoring may be modified to improve acceptability.

Inclusion:

1. Healthy males or females between 18 and 50 years of age inclusive.
2. BMI 20-30 kg/m^2.

Exclusion:

1. Pregnant or currently lactating.
2. Taking any prescription medications.
3. Taking any OTC medications that cannot be stopped for test days.
4. Allergic to any ingredients contained in the bar.
5. Other conditions or situations that would interfere with the study or the participant's safety as determined by the investigators.

Testing Visit: The participants will come to the Pennington Biomedical Outpatient Clinic having had nothing but water from 10pm the prior night for the taste test. After appropriate written consent, participants will have their height and weight measured, BMI calculated and vital signs measured. Participants will also be asked about any medications that they may be taking. Following completion of these procedures, each participant will be

provided with a food bar and asked to consume the bar. After consumption, the participant will complete visual analog scales to rate the following: visual appeal, smell, taste, texture, aftertaste, and overall pleasantness.

Data Analysis: The visual analog scales will be reviewed and minimum thresholds will be set for each parameter. 6 out of 10 participants must rate the bar as acceptable to be considered a successful bar.

Phase 1 - Schedule of events

Test/Visit	Test Day
Taste Test	x
Visual Analog Scale	x
Adverse Events	x

Phase 2

Once an acceptable bar has been developed, phase 2 will begin.

Aim 3: Measure safety parameters (blood chemistry) pre and post bar consumption.

Aim 4: Measure bioactive compounds in the blood to determine absorption and PK parameters.

Study Design: 10 healthy participants will be enrolled into the study. The study will have a screening visit and a testing visit.

Inclusion:

1. Healthy males or females between 18 and 50 years of age inclusive.
2. BMI criteria 20-30 kg/m^2.

Exclusion:

1. Pregnant or currently lactating.
2. Taking any prescription medications.
3. Taking an OTC medications that cannot be stopped on testing day
4. Allergic to any ingredients contained in the bar.
5. A participant in phase 1 of the study.

56 Other conditions or situations that would interfere with the study or the participant's safety as determined by the investigators.

Screening visit: Participants will come to the screening visit having had nothing but water from 10pm the prior night. They will sign an informed consent after having all questions answered, complete a medical history questionnaire, have blood pressure, pulse, weight and height measured, and have blood drawn from an arm vein for a chemistry panel (less 2 teaspoons of blood). The chemistry panel will provide basic health information and participants may be excluded for abnormal lab values as determined by the study physician.

Testing Visit: The testing day will occur within 30 days of the screening visit. The participants will come back to the Pennington Biomedical Outpatient Clinic having had nothing but water from 10pm the prior night for the

testing visit. Each participant will be provided with a food bar and asked to consume the bar within 10 minutes. Blood samples will be taken prior to consumption of the bar (-10 minutes), baseline (time 0 after the bar is consumed) and at times 30, 60, 120 and 180 minutes post ingestion of the bar for glucose, insulin and bioactives.

Statistics: Normally distributed data will be analyzed by t-test and non-parametric data will be analyzed by chi squared testing or another appropriate statistical test.

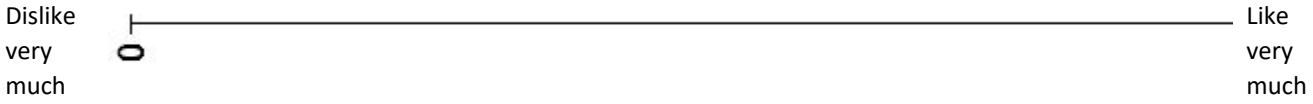
Phase 2 - Schedule of events

Test/Visit	Screening	Test Day
Consent	x	
Chemistry Panel	x	x
Medical Questionnaire	x	
BP, Pulse & weight	x	
Height	x	
Bioactives		x
Taste Test		x
Visual Analog Scale		x
Adverse Events		x

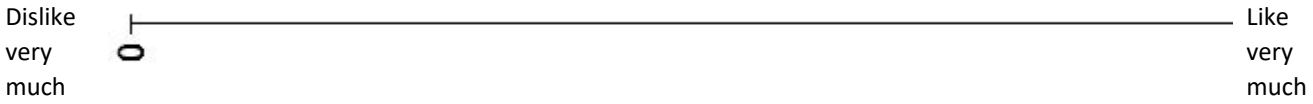
Acceptability Visual Analog Questionnaire

Palatability Ratings

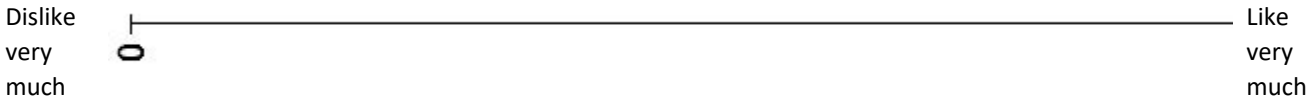
Visual Appeal



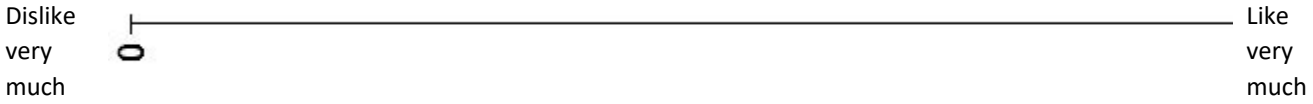
Smell



Taste



Texture



Aftertaste

Pleasant/Unpleasant (Please check)

Overall Pleasantness