14 CLINICAL STUDIES

14.1 Healthy Adults

The short-term safety and digestibility of SBI was evaluated in a pilot trial conducted in 12 healthy adult subjects. In the first part of the study (double-blind, cross-over), subjects received either pudding or pudding which contained 10 g SBI in random order on 2 consecutive days. In the second part of the study, subjects consumed 2.5 g SBI in pudding twice daily for 14 days. There were 6 males age 19-25 years (mean = 23.3 years) and six females age 22-42 years (mean = 29.3 years). All were normal weight. Body mass index values for males and females ranged from 22.0-30.2 and 19.0-22.3, respectively, with mean values of 24.1 and 20.1. Results of the first part of the study demonstrated that some protein in SBI is digested in the adult GI tract. Overall AUC for leucine in the SBI group was significantly higher ($p < 0.05$) compared to the non-SBI group. An increase in plasma amino acid levels compared to baseline is an indication of protein digestion and amino acid absorption. No absorbed, intact bovine immunoglobulin was detected in plasma. Enzyme-linked immunosorbent assays were performed on stool samples for IgG, which was present in stool on day 14 of the second part of the study, demonstrating that IgG activity is retained with passage through the GI tract. Reported AEs included increased urination (3 subjects), stomach cramps (3 subjects), fatigue (2 subjects), and headache (2 subjects), as well as sore throat, softened stools, nausea, constipation, and irritability (1 subject each). The pudding containing SBI was generally well-tolerated by the subjects during the single bolus dose and over 14 days of twice-daily ingestion.