6 ADVERSE REACTIONS

6.1 Clinical Trial Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a product cannot be directly compared to rates in the clinical trials of another product and may not reflect the rates observed in-market when prescribed to patients with co-morbidities or taking multiple pharmaceutical agents. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to product use and for approximating rates of side effects. There are no treatment-emergent adverse events (AEs) associated or related with the use of 1.25 to 10 g of SBI per day in ENTERAGAM found in clinical trials with a total of over 200 subjects or patients. Infants ranging in age from 6 to 25 months were administered between 1.25 to 2 g of SBI per day in ENTERAGAM for up to 8 months. Adults ranging in age from 18 to 70 yrs were administered 5 to 10 g of ENTERAGAM per day for 2 days up to 48 weeks. The most commonly reported AEs in clinical studies (incidence 2-5%) included mild nausea, constipation, stomach cramps, headache, and increased urination.