

CHARACTERIZING SERIOUS ADVERSE DRUG EVENTS ASSOCIATED WITH WEIGHT LOSS SUPPLEMENTS REPORTED TO THE FDA (B4), Phebe Kwon, Candy Tsourounis, Cathi Dennehy. UCSF Medical Center, San Francisco, California (Phebe.Kwon@ucsf.edu) IRB approved.

According to the Dietary Supplement Health and Education Act (DSHEA), clinical trials demonstrating safety in humans are not required prior to marketing of a dietary supplement. As such, greater importance is placed on evaluating postmarketing safety surveillance data. As of December 2007, new legislation requires supplement manufacturers report all serious adverse drug events associated with their products to the FDA. This study aims to characterize serious adverse event data associated with common dietary supplement weight loss ingredients (e.g. *Citrus aurantium*, Bitter orange, Caffeine, Cola nut, Guarana, Country mallow, Yerba mate, Chromium picolinate, Green tea extract, Hoodia, Ginseng, and St. John's Wort) reported to the Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS) in 2008. This retrospective review will include all reports and will be characterized for outcome, type of adverse event, report source, product or supplement involved, route of administration, amount used, duration of use and patient age and sex. Results and Conclusions will be presented.