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CHARACTERIZING SERIOUS ADVERSE DRUG EVENTS ASSOCIATED WITH VITAMINS AND MINERALS REPORTED TO THE FDA (B4), Sarah Brody, Cathi Dennehy, Candy Tsourounis. UC San Francisco, San Francisco, CA (Sarah.Brody@ucsf.edu) IRB approved.

Vitamins are the top selling supplements, primarily because they are used in all stages of life. This study's objective was to characterize serious adverse drug events associated with vitamins and minerals reported to the FDA after implementation of the Dietary Supplement and Nonprescription Drug Consumer Protection Act in December 2007. The Food and Drug Administration Center for Food Safety and Applied Nutrition Adverse Events Reporting System was retrospectively reviewed for severe reports submitted in a defined set of months during calendar year 2008. Data including product involved, manufacturer, amount taken, duration of therapy, adverse event, concomitant medications, supplements and disease states, age, sex, report source and the nature of the intervention were recorded and analyzed. Preliminary findings for January 2008 suggest most reports are vitamin and or mineral related. Causality is very difficult to determine according to the information provided in each case. The current format of the database is difficult to navigate and interpret. Significant improvements are recommended.