Preliminary Data on Labeled Levels for 21 Vitamins and Minerals in Adult Multivitamins and Minerals

**SAMPLING PLAN:**

1. NDL has conducted a national sampling of adult MVMs for two purposes:
   - Provide nationally representative estimates for nutrients in products commonly reported by the U.S. population (Top 10 Market Shares (TMS) products).
   - Obtain additional data for lower-market-share (LMS) products for the purpose of conducting statistical-regression analysis across a range of labeled nutrient levels.

2. NDL developed a multi-stage probability proportional to size (PPS) sampling plan for food and beverages in cooperation with statisticians from the USDA National Agricultural Statistics Service (NASS) (Peterson et al., 2007). The purpose of the sampling plan is to select sample units from multiple geographic areas of the U.S. that, when analyzed, can provide reliable and representative estimates of means and variability for nutrient content. Similarly, NDL has consulted with statisticians to set up a sampling frame and 3 product-specific plans for the collection of dietary supplement product samples to ensure that samples being analyzed are representative of the market.

3. Representative products, brands, forms, and market channels for products were identified using compiled data from nutrition sales report, market research reports, NHANES, and national shopper surveys.

4. Frequently reported products were identified as top products. After applying an algorithm to assign weighted values, a trend/product list was generated where products for Strata 1 and 2 were identified. (NOTE: Discontinued products were reviewed subsequently.)

5. Finalized list of stores and products organized by market channel. A product list was distributed to contracted shopping vendor. Products identified as mass market or natural/health were purchased by regional shoppers in six regions - AL, KY, CO, CA, MI, MD. Three unique lots were the goal for each product. Direct sales products were purchased by NDL staff from the internet and other direct sales channel sources. Two unique lots were the goal for each product.

6. Each purchased product was recorded by region and lot number. Ingredient, ingredient source, and percent daily value (DV) for each product were recorded separately.

7. Labeled levels, obtained from product Supplement Fact panels, were compiled to obtain ingredient ranges (per serving levels). (Table 1)

**NEXT STEPS:**

1. A final list of products to be analyzed was being compiled based on a statistical evaluation of market channel breakdown and label levels.

2. Adult MVM-2 products will be analyzed for 21 vitamins and minerals using validated analytical methods at each contracted laboratory. Each batch of sample will be analyzed using the same reference material (NIST 3280) and two retail in-house controls to monitor accuracy and precision.

3. Statistical regression analysis will be employed to evaluate percent difference from label across a wide range of labeled levels as shown in Table 1.

**DEFINITION OF A DIETARY SUPPLEMENT (DSHEA):**

The Dietary Supplement Health and Education Act (DSHEA) of 1994, defines a dietary supplement as:

- Any product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of these ingredients.
- Intended for use in the diet as a supplement to achieve the total dietary intake in amounts normally not ingested in the food diet without the supplement.
- Not represented for use as a conventional food or as the sole item of a meal or diet.
- Not typically consumed in a physiological activity or role.
- Not used as a therapeutic, medical, or diagnostic food.

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