

CCNFSDU, Bonn, 3-7 November 2003

LABEL CLAIMS—Health Claims, Structure-Functions Claims and the Regulatory Boundaries Between Food and Drug

1. **Classical nutritional deficiency diseases.** For these diseases, foods and nutrients are used to “treat, cure, mitigate, prevent and reduce the risk” of the diseases. Certainly, most people use food in a way that will “prevent” such diseases, without need to physician or pharmacist. Examples of these nutrient-disease pairs include:
 - a. Iron—**anemia** (supplements or fortification programs known as enrichment)
 - b. Folic acid—**anemia** (supplements or fortification)
 - c. Vitamin B12—**anemia** (supplements or fortification)
 - d. Niacins—**pellagra**
 - e. Thiamin—**beri beri**
 - f. Vitamin C—**scurvy**

2. **Nutrient responsive diseases.** For these diseases, foods and nutrients are used to reduce the incidence, both decreasing the probability of individuals developing the disease, or delaying the premature onset. The causes of such diseases are clearly multi-factorial, but intakes of specific nutrients are major factors. That is, increased nutrient intake significantly decreases the risk of such diseases. In some example, the amounts of nutrients needed to achieve the effect is well above the currently established Recommended Dietary Allowances (RDA): Examples of these nutrient-disease pairs include:
 - a. Fluoride—**dental caries** (water fluoridation, some supplements)
 - b. Folic acid—**neural tube defects** (supplementation and fortification)
 - c. Combination of folic acid and vitamins B6 and B12—**control plasma concentrations of homocysteine, which is becoming recognized as a risk factor for heart disease** (supplementation)
 - d. Strong but still emerging evidence—**Selenium—reduces incidence (but not treatment) of some types of cancer** (supplementation)

In the examples above, the quantities of nutrients needed are safe for self-selection use by the consumer with no medical supervision—if products are formulated to appropriate maximums based on risk assessment, and not the RDA. When the disease develops, medical supervision is needed, but there is no need for supervision by the physician or pharmacist during the early prevention phase. It is the disease and not the nutrient that requires medical supervision.

3. **Nutrients used as drugs.** In the example below, very high doses of a specific form of a vitamin has been shown to be an effective pharmacological agent in controlling an important risk factor for a major disease.
 - a. Nicotinic acid—treating hyperlipidemia

Nicotinic acid can be a very effective (and expensive) drug to control cholesterol and triglyceride concentrations in the plasma. The dosages required for this effect are three or four times greater than can be used safely for self-selection by the consumer. Any consumer taking nicotinic acid quantities that are effective for this purpose should be under medical supervision and appropriate monitoring for potential adverse effects on the liver. Persons using such products at effective intakes should be under medical supervision and monitoring to guard against the real but relatively low risk of adverse effects on the liver.