The National Kidney Foundation appreciates the opportunity to comment on Food Labeling: Revision of the Nutrition and Supplement Facts Label (FDA–2012–N–1210). One in three Americans over age 20 — 73 Million people — is at risk for kidney disease because of high blood pressure, diabetes, or a family history of kidney disease and 26 million people already have kidney disease. NKF is America’s largest and oldest health organization dedicated to the awareness, prevention and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF is the founding sponsor of the Kidney Disease Improving Global Outcomes (KDIGO) initiative and has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD) and related complications since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We applaud the efforts of the FDA to provide consumers with more detailed information they need to make nutritional decisions to live healthier lives. We also support the FDA’s efforts to address the obesity crisis through these proposed changes to food labels. Studies have shown obesity is an indirect cause of kidney disease and recent evidence is suggesting a more direct link between obesity and kidney disease even in the absence of diabetes or hypertension.1 2 3

Kidney disease, like obesity, is also a large public health concern that leads to increased morbidity and mortality. However, outcomes are improved when patients follow a kidney specific diet. Nutritional recommendations for kidney patients are markedly different from the general public and nutrition education efforts need to be supported by more transparent and clearer food labeling. This can be accomplished by listing specific measurements of nutrients, which helps the average consumer as well as the consumer who requires a specialized diet. For these reasons NKF strongly endorses the FDA’s proposal to include potassium, calcium milligrams (mg), and to lower the recommended sodium upper limit on food labels. However, given the health implications to the general public and those with kidney disease we strongly encourage the FDA to also include phosphorus content on the food label.

Controlling potassium and calcium intake for people with CKD
While most Americans need to increase their potassium and calcium intake individuals with CKD need to limit their intake. Including potassium and calcium milligrams provides essential information to people with CKD. Too much potassium and calcium increases the risk of cardiovascular events in people with CKD. In 2006 the National Kidney Foundation and the Academy of Nutrition and Dietetics 4 conducted a survey of people with CKD to see how useful the nutrition labels were for them. Eighty-three percent of the total respondents indicated that they read the food label for the amounts of nutrients when they decide to buy or eat a food or beverage. Eighty-nine percent believe it would be useful to have potassium content on the Nutrition Fact Panel. Further, 86% would be more comfortable buying the food if potassium were listed on the food label. More than half (58% of respondents had decided at some time not to buy a food or beverage because the amount of potassium was not listed. Two thirds of

4 At the time called the American Dietetics Association
the survey participants responded that they did not know how much calcium was contained in a serving of food that is described on the food label as 25% DV. These findings were provided to the FDA in 2007 in response to the previous proposed food labeling revisions. We expect this recent proposal, to include the actual units of both potassium and calcium, will help those with CKD who are educated about their dietary needs make better informed decisions about the foods they consume. We strongly encourage the FDA to move forward with this proposal.

**Controlling sodium intake for the general population**

While we are pleased the FDA's lowering of the upper sodium limit from 2,400 mg to 2,300 mg we strongly encourage the FDA to lower the recommended upper limit to 1500 mg of sodium, which is recommended by the American Heart Association.5 There are strong links between blood pressure and sodium intake and given the prevalence of high blood pressure (one-third of Americans have hypertension with another third in the prehypertension range)6 and we believe more needs to be done to encourage food producers to lower sodium content and consumers to lower their intake.

**The importance of disclosing phosphorus units on the food label**

While overall supportive of the proposed change NKF remains concerned that disclosing phosphorus content on food labels is not required and is not included in the proposed regulation. For years NKF has advocated that the FDA require disclosure of phosphorus on food labels because of the importance of the information to people with kidney disease. In light of new evidence that shows high phosphorus intake is also a serious health concern for the general public, we again strongly encourage the FDA to modify its proposal and require phosphorus, both naturally occurring and in additive form, on food labels. The kidney community is united in this request. Disclosing phosphorus also aligns with FDA’s criteria in the proposed rule for considering when to require labeling of nutrients because there is “evidence of a relationship between the nutrient and a chronic disease” and “health related condition.” Americans consume on average much more than the Institute of Medicine’s (IOM) recommended tolerable upper intake levels for phosphorus.7 Recent studies indicate that higher levels of phosphorus can increase mortality, even if those levels are within the normal range.8

The kidney is responsible for the homeostasis of phosphorus through an effect of several hormones that increase the urinary excretion of phosphorus. While these mechanisms of enhancing urinary phosphorus excretion are effective in maintaining normal blood phosphorus levels until very late in the course of the progression of kidney disease, the persistent elevation of these hormones cause bone

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disease, heart disease, and are associated with mortality in patients with CKD. This emerging data support the effect phosphorus has on the public’s health and on development of chronic disease.

Restricting dietary phosphorus intake is essential in patients with kidney disease as well. However, the increasing use of additives and the lack of mandatory labeling of phosphorus content pose significant—and often insurmountable—challenges to patients and their families from adhering to these important recommendations. Two recent scientific meetings highlighted the importance of kidney patients’ phosphorus regulation: A scientific consensus symposium sponsored by the National Kidney Foundation in 2012 and a symposium at the Annual Meeting in Experimental Biology in 2013 at a session entitled “Dietary Phosphorus Excess: A risk factor in chronic bone, kidney and cardiovascular disease” sponsored by the American Society of Nutrition and American Society of Nephrology.

Studies of patients with kidney disease demonstrate that high phosphorus intake, whether in the form of additives or meat, leads to changes in hormones that are shown to be associated with mortality. In particular, individuals that consume processed foods with phosphorus additives (most commonly in the form of sodium phosphate and its derivatives) have increased urinary sodium and phosphorus compared to similar foods without additives, indicating significant absorption of these nutrients from the additives. In one study of patients on dialysis, simply instructing patients to avoid processed foods (where most additives are found) led to a reduction in blood phosphorus levels that allowed reduction in phosphate binder prescriptions.

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11 Gutierrez OM. The connection between dietary phosphorus, cardiovascular disease, and mortality: where we stand and what we need to know. Advances in nutrition 2013;4:723-729.


Another study found that over 45% of the best-selling grocery items contained phosphorus additives, and these items typically cost less and are eaten more commonly in individuals of lower socioeconomic status. The use of phosphate containing food additives has increased substantially over the last several years. Analyses of processed foods that contain phosphate additives indicate that these increase the food phosphorus content by 70%. Analyses of meat and poultry products demonstrate that additives increase both the phosphorus and potassium intake by two to three fold, respectively, both leading to adverse consequences in patients with CKD.

We strongly recommend that FDA make labeling of phosphorus content a mandatory part of the label as opposed to a voluntary part of the label. This change would ideally be further subdivided into natural content of phosphorus versus added phosphates, similar to the proposed changes for distinguishing between sugar content of food versus added sugar as detailed in Section II Proposed Rule, D. Carbohydrates, 2. Sugars and 3. Added Sugars (p 11902). In the Section II Proposed Rule, H. Essential Vitamins and Minerals of Public Health Significance, Essential Vitamins and Minerals that are Mandatory (p 11921) the rule discusses the role of upper limits of safety on additives that are generally regarded as safe.

The evidence described above supports that phosphate additives should also have an upper limit of safety. The proposed rule does not plan changes to micronutrients such as phosphorus. However, given the considerable evidence that phosphorus is associated with adverse outcomes in kidney disease—which affects more than 26 million Americans—and the fact that phosphorus is a widespread, unregulated food additive associated with mortality and morbidity in the general public as well—we believe that labeling the micronutrient be mandatory.

We appreciate the opportunity to comment on this important proposed regulation.

Sincerely,

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