July 15, 2025

The Honorable Martin A. Makary M.D., M.P.H.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dockets and Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: FDA-2024-N-2910- Food Labeling: Front-of-Package Nutrition Information

Dear Dr. Makary,

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on Food Labeling: Front-of-Package Nutrition Information.

Chronic kidney disease (CKD) is a progressive condition characterized with the gradual loss of kidney function[i]. It affects approximately 37 million Americans, or about 1 in 7 adults, and its prevalence is projected to rise[ii]. CKD poses an increasing public health crisis resulting in considerable morbidity and growing health care expenditures. The U.S. Medicare program spends more than $150 billion each year managing kidney diseases, including $50 billion for kidney failure patients alone[iii]. Despite its widespread impact, CKD is a clinically silent and, until its latest stages, an asymptomatic disease that is often not detected until patients develop kidney failure and an urgent need for dialysis or a kidney transplant. Given these realities, primary prevention of CKD, particularly through the identification of modifiable lifestyle factors that can delay or prevent the onset and progression of CKD in the general population, is essential to reducing its burden on both individuals and the health care system.

The kidneys are important in metabolism and regulation of many nutrients. For example, people with advanced kidney disease may become overloaded with sodium very easily and with serious consequences. Further, the kidney is involved with balancing

micronutrients, including potassium, calcium, vitamin D, and phosphorus. For Americans with advanced kidney disease and for those with kidney failure, carefully regulating consumption of these micronutrients is critical to maintaining the best possible health and quality of life. Phosphorus, which is an additive in many foods and occurs naturally in others, may be particularly harmful for people with advanced CKD. However, despite its importance, phosphorus is missing from existing food labels.

The nearly 22,000 health professionals who constitute ASN's membership instruct patients with kidney disease to carefully read food labels in order to avoid adverse consequences of inappropriate intake of sodium, potassium, and phosphorus. This is very difficult given the absence of phosphorus from existing food labels. Recognizing the importance of diet in the management of kidney disease, ASN strongly recommends the FDA to include phosphorus content on both the existing Nutrition Facts Label and the proposed Front-of-Package Nutrition Information Box.

ASN Commends the FDA's Front-of-Package Label Proposal

ASN commends the FDA's proposal to require foods that contain a Nutrition Facts label to bear an additional "Front-of-Package Nutrition Information Box" on the principal display panel that details and interprets the relative amount of saturated fat, sodium, and added sugars. As noted above, the kidney regulates sodium and water metabolism and is integrally involved in the development of hypertension. Patients with kidney disease are encouraged to reduce sodium intake to assist in managing hypertension, volume overload and edema, and the proposed changes to the label will be instrumental in empowering patients to take more control over their sodium consumption. Ultimately, this change may help improve the lives of millions of Americans with kidney disease who are working, in partnership with their nephrology health professionals, to better slow the progression of their kidney disease or minimize its effect on living a normal, healthy life.

ASN Expresses Concern Over the Continued Omission of Phosphorus Content from Nutrition Labeling

In 2014, the Nutrition Facts Label underwent its first revision in 20 years. The proposed changes were intended to improve consumer understanding, such as increasing the font size for calories and including added sugars in the total amount of sugar. During the public comment period, ASN, along with others in the kidney health community, strongly advocated for mandatory phosphorus labeling, citing research that links high phosphorus intake and high phosphorus levels in the blood with increased morbidity and mortality in individuals with chronic kidney disease, including those on dialysis, and even among individuals in the general population.

Despite these concerns, the FDA declined to include phosphorus in its final 2016 rule. The rationale provided by the agency stated that the Nutrition Facts Label is designed to help consumers make healthier dietary choices, not to manage chronic diseases. In the same rule, however, the FDA justified the inclusion of vitamin D and potassium by identifying them as “vitamins and minerals of public health significance” that are important for bone development, general health, and blood pressure regulation[iv]. These nutrients were included on the label due to their recognized health benefits and the fact that they are commonly under consumed by the population, while phosphorus was excluded.

ASN remains disappointed that the FDA continues to omit phosphorus content from both the current Nutrition Facts label as well as the newly proposed Front-of-Package Nutrition Information Box, despite its clear relevance to individuals with CKD, for whom phosphorus management is critical to health outcomes. Phosphorus can occur naturally in the form of food, or as a component in commonly used food additives. The amount of phosphorus in the American diet has increased considerably, primarily from phosphorus-containing additives in convenience and fast foods[v]. The kidneys are responsible for the homeostasis of phosphorus through the effects of several hormones that maintain normal blood phosphorus levels until advanced CKD develops. Unfortunately, the persistent elevation of these hormones causes bone disease and cardiovascular disease and are associated with increased mortality in patients with CKD.

Limiting dietary phosphorus intake is an important therapeutic strategy for patients with kidney disease. However, the growing use of phosphorus-containing additives, combined with the lack of mandatory labeling of phosphorus content, creates significant and often insurmountable challenges for patients and their families trying to follow these critical recommendations. Because phosphorus is not required to be listed on food labels, the millions of Americans living with kidney diseases are left to decipher the fine print on ingredient lists, trying to recognize and interpret the complex names of more than 240 phosphorus additives currently in use. Even then, there is typically no information about how much phosphorus the food contains. In September 2025, ASN will publish Kidney Health Guidance detailing available strategies to reduce the risks associated with potassium and phosphorus additives in the *Journal of the American Society of Nephrology*. This clinical guidance covers the current state of science regarding the role of potassium and phosphorus food additives in patients with kidney diseases but is limited by the lack of information on phosphorus content in food.

Studies have shown that, even in individuals without kidney disease, those in the highest quartile of phosphorus levels within the normal range face an increased risk of mortality[vi]. Excessive phosphorus intake, particularly from food additives, poses significant health concerns. Elevated phosphorus levels have been linked to

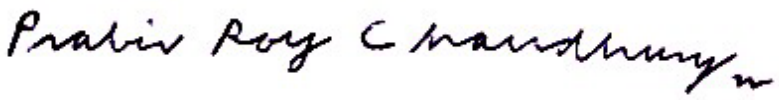
cardiovascular disease, bone loss, and harmful calcium deposits in soft tissues such as blood vessels, lungs, eyes, and the heart[vii].

Conclusion

ASN appreciates the FDA's commitment to improving the burden of chronic disease through clearer and more accessible labeling, including the proposed Front-of-Package Nutrition Box. Highlighting saturated fat, sodium, and added sugars is a valuable step, particularly considering sodium's critical role in managing chronic kidney disease. However, the continued omission of phosphorus remains a significant concern, given its direct impact on individuals with CKD and the general population. Including phosphorus on both the Nutrition Facts label and the proposed Front-of-Package labeling would support more informed choices for this vulnerable population. These changes would represent meaningful progress in helping to reduce the burden of both CKD and ESRD and the associated healthcare costs by empowering patients to better manage their health through diet.

To discuss this letter further, please contact David White, ASN Senior Regulatory and Quality Officer, at dwhite@asnonline.org.

Sincerely,



Prabir Roy-Chaudhury, MD, PhD, FASN
President

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[i] Chronic kidney disease - Symptoms and causes - Mayo Clinic
[ii] Kidney Disease Statistics for the United States - NIDDK
[iii] Kidney Disease Statistics for the United States - NIDDK
[iv] 2016-0030.pdf (SECURED)
[v] Takeda E, Yamamoto H, Yamanaka-Okumura H, Taketani Y. Increasing dietary phosphorus intake from food additives: potential for negative impact on bone health. Adv Nutr. 2014 Jan 1;5(1):92-7. doi: 10.3945/an.113.004002. PMID: 24425727; PMCID: PMC3884105.
[vi] Dominguez JR, Kestenbaum B, Chonchol M, Block G, Laughlin GA, Lewis CE, Katz R, Barrett-Connor E, Cummings S, Orwoll ES, Ix JH; Osteoporotic Fractures in Men (MrOS) Study Research Group. Relationships between serum and urine phosphorus with all-cause and cardiovascular mortality: the Osteoporotic Fractures in Men (MrOS) Study. Am J Kidney Dis. 2013 Apr;61(4):555-63. doi: 10.1053/j.ajkd.2012.11.033. Epub 2012 Dec 20. PMID: 23261120; PMCID: PMC3815620.
[vii] Association of Total, Added, and Natural Phosphorus Intakes with Biomarkers of Health Status and Mortality in Healthy Adults in the United States