CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

Submitted via www.regulations.gov
Docket No. FDA- 2021-D-0528

November 7, 2022 - CORRECTED

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

Re: Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over the Counter and Prescription Drug Products; FR Vol. 87, No. 174, 55444-6, September 9, 2022; Industry Comments

Dear Sir or Madam,

The Consumer Healthcare Products Association[1] (CHPA) submits these comments on a draft guidance by U.S. Food and Drug Administration (FDA or Agency) on Quantitative Labeling for Sodium, Potassium and Phosphorous for Human Over-the-Counter and Prescription Drug Products. For more than 141 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medicines, dietary supplements and consumer medical devices. Our members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

CHPA acknowledges that the draft guidance provides information and recommendations concerning the quantification of sodium, potassium, and phosphorus for both OTC and prescription (Rx) drug product labeling because (1) these substances are common constituents of ingredients that can be present in drug products in amounts that may represent a significant portion of an individual's total daily intake and (2) dietary restriction of these constituents is often a recommended practice for various diseases that affect a substantial number of patients in the U.S. population. CHPA also acknowledges that quantifying these constituents would help health care providers manage their patients' total daily intake when treating conditions such as heart failure, hypertension, or chronic kidney disease

After a thorough review of this draft guidance document, CHPA requests the following modifications to this guidance document.

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including Over-the-Counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

General Comments

Guidance Recommendations Expand Beyond Current Labeling Requirements listed in 21 CFR 201.64 and 201.72

The Administrative Procedure Act ("APA") identifies guidance documents that set forth an agency's interpretation of a statute or regulation.[2] This concept is reflected by FDA in the introduction of this guidance, which states that this draft guidance restates the legal requirements set forth in current regulations for sodium and potassium in labeling for OTC products, but the guidance goes further and provides recommendations for the labeling of phosphorus.

CHPA believes the current labeling regulations in 21 CFR 201.64 and 201.72 are clear, serve the consumer and industry well and do not need additional clarification for phosphorous labeling recommendation via guidance. We do not support modifying or expanding current regulations on labeling via guidance.

Specific Comments

1) The final guidance should omit all references to sodium and potassium in OTC drug products since the guidance is not consistent with or as comprehensive as the regulations established for both sodium and potassium content.

    a. The consumer healthcare industry already has specific regulations for the labeling of sodium content (21 CFR 201.64) and for labeling potassium content (21 CFR 201.72) for all OTC drug products. These regulations are more detailed and contain considerably more labeling requirements than recommendations in the proposed guidance document. For example, the draft guidance does not address oral products that are excluded from sodium labeling requirements such as dentifrices, mouthwashes, or mouth rinses. The guidance does not address allowable labeling claims for sodium content with OTC drug products, such as the labeling with the terms sodium free, very low sodium and low sodium.
    b. The draft guidance states the Agency's intent to expand the labeling requirements for prescription drugs, so they are required to contain a per dosage unit content statement. We note that both potassium and sodium labeling regulations for OTC drug (21 CFR 201.72 and 21 CFR 201.64) already contain this requirement for labeling both sodium and potassium content per dosage unit. For this reason, the guidance document is not needed for OTC drug product labeling.

2) CHPA recommends that the Agency promulgate separate labeling regulations for phosphorous content for OTC drug products.

---

[2] Pub. L. 89–554, § 553(b), 80 Stat. 383 (1966).

a. CHPA requests that the Agency be consistent with its regulatory approach on how OTC drug products are labeled for content. Current regulations exist for the labeling requirements for sodium and potassium on OTC drug products. CHPA recommends that the Agency not use a guidance approach for the labeling of phosphorus content. If phosphorus content is as important to patient health as sodium and potassium, then phosphorous labeling should be regulated by the rulemaking process with a full description of requirements. Proposed rulemaking would allow for the Agency and industry to have ongoing public dialogue and public vetting of comments that would allow for a discussion on phosphorous labeling location, precise statements, product type labeling exemptions and language on allowable claims. The public rulemaking process should not be displaced by a guidance document approach.

CHPA members appreciate the opportunity to provide regulatory input on this draft guidance document. Feel free to contact me with any questions.

Sincerely,

Barbara A. Kochanowski, Ph.D.
Senior Vice President, Regulatory & Scientific Affairs
bkochanowski@chpa.org