Docket No. FDA-2016-D-2335

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

FOOD LABELING: NUTRIENT CONTENT CLAIMS; DEFINITION OF TERM "HEALTHY"

February 16, 2023

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

The current regulation governing use of the term "healthy" (and related terms, such as "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness") as an implied nutrient content claim on the label or in labeling of a food is codified at 21 C.F.R. § 101.65(d)(2). This regulation establishes specific criteria for this implied nutrient content claim related to the levels of fat, saturated fat, cholesterol, and other nutrients present in a food subject to such a claim, irrespective of the food's ingredients.

On September 28, 2016, the U.S. Food and Drug Administration (FDA or the Agency) published a Federal Register notice[1] in which the Agency invited comments on the term "healthy" as a nutrient content claim in the context of food labeling and on specific questions contained in the notice. AHPA timely submitted comments in response to this notice.[2]

FDA also issued a separate Federal Register notice[3] in which it announced the availability of a guidance document titled "Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry" (the "Healthy" Guidance). In this second Federal Register notice, as well as in the "Healthy" Guidance, FDA stated its intention to exercise enforcement discretion with respect to some of the existing criteria for the implied nutrient content claim "healthy" when the subject food meets alternative nutrient criteria described in the "Healthy" Guidance. This enforcement

[1] Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments. Proposed Rule. 81 Fed. Reg. 66,562 (September 28, 2016).

[2] Comments of the American Herbal Products Association on FDA's Request for Comments on Use of the Term "Healthy" in Labeling of Human Food Products (April 26, 2017).

[3] Use of the Term "Healthy" in the Labeling of Human Food Products: Guidance for Industry; Availability. 81 Fed. Reg. 66,527 (September 28, 2016).

discretion would continue until such time as the Agency amends the rule at 21 C.F.R. § 101.65.

On September 29, 2022, FDA issued a proposed rule to update the regulation governing "healthy" claims for food products (including dietary supplements) to better align it with current federal dietary guidelines[4] (the Proposed Rule). Under the Proposed Rule, criteria for the use of "healthy" for a particular food would vary and depend upon the food group(s) and subgroup(s) from the USDA Dietary Guidelines 2020-2025[5](the Dietary Guidelines) applicable to the subject food. Foods may bear a "healthy" claim when they contain a specified quantity from a particular food group or combination of groups (food group equivalent) and meet associated limits for added sugar, sodium, and saturated fat. Among other provisions, plain and carbonated water without any flavoring or additional ingredients may also bear the "healthy" claim without meeting either the food group equivalence requirements or nutrient limits.

I. The Proposed Rule should not restrict the use of "healthy" claims on dietary supplements

The Proposed Rule could potentially prohibit the use of "healthy" on any dietary supplement, as dietary supplements would not, in most cases, comply with the food group equivalent requirements. As discussed in further detail below, completely prohibiting the use of "healthy" on dietary supplements would prove inconsistent with the goals of the Proposed Rule and the Dietary Guidelines to promote a healthy dietary practice and would create confusion regarding the use of otherwise lawful claims on dietary supplements (i.e., "supports a healthy heart").

As a result, AHPA requests that FDA exempt "dietary supplements" as a category from the Proposed Rule.

[4] Food Labeling: Nutrient Content Claims; Definition of Term "Healthy." Proposed Rule, 87 Fed. Reg. 59,168 (Sept. 29, 2022) ("Proposed Rule").

[5] U.S. Department of Agriculture and U.S. Department of Health and Human Services, Dietary Guidelines for Americans, 2020-2025, 9th Edition (Dec. 2020) ("Dietary Guidelines").

A. Restricting the use of "healthy" on dietary supplements would prove inconsistent with the goals of the Proposed Rule and the Dietary Guidelines to create and maintain healthy dietary practices

Dietary supplement products are specifically "intended to supplement the diet," including products intended to "increas[e] the total dietary intake" of beneficial substances.[6] The Dietary Guidelines explicitly state that "dietary supplements may be useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts."[7] The Dietary Guidelines also acknowledge that obtaining recommended intakes of certain nutrients, such as vitamin D, is "harder to achieve through natural sources from diet alone" and require either fortification or supplementation.[8] As such, dietary supplements are useful, and in some cases necessary, in "creating a diet that is consistent with dietary recommendations" as per proposed 21 C.F.R. § 101.65(d)(3).

A rule that could potentially prohibit the use of "healthy" on dietary supplement labels and labeling would create consumer confusion regarding the benefits of dietary supplements, which could lead consumers to incorrectly believe that dietary supplements are not useful in creating and maintaining healthy dietary practices. As noted above, the Dietary Guidelines acknowledge that supplementation is often necessary to obtain adequate nutrient intake and in turn maintain a healthy dietary practice. Further, effectively prohibiting the use of "healthy" on dietary supplements but permitting the use of "healthy" on certain conventional food products that contain comparable or even lower amounts of vitamins, minerals, and other essential nutrients could lead to the unsupported and inaccurate impression that nutrients gained from dietary supplements are inferior to those found in conventional foods. Indeed, FDA regulations prohibit labeling that represents, suggests, or implies that a natural vitamin in a food is superior to an added vitamin.[9] In both cases, these incorrect assumptions would lead to a reduction in the use of dietary supplements to address nutrient deficits, creating public health harm.

[6] 21 U.S.C. § 321(ff)(1).

[7] Dietary Guidelines, at 36.

[8] *Id.*

[9] 21 C.F.R. § 101.9(k)(4).

B. Restricting the use of "healthy" on dietary supplements would create confusion regarding the use of otherwise lawful claims on dietary supplements

Additionally, restriction of the use of "healthy" on dietary supplement labels and labeling would create confusion regarding otherwise lawful and truthful statements regarding the health benefits of dietary supplement use, which could invite civil litigation over these otherwise lawful claims.

Under certain circumstances, federal law permits statements made for dietary supplements that: claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States; describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans; characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function; or describe general well-being from consumption of a nutrient or other dietary ingredient.[10] In promulgating the final rule to implement this statutory provision, FDA provided several examples of such lawful claims for dietary supplements that include the word "healthy,"[11] and, in that final rule, the Agency differentiates unlawful "disease claims" from lawful "statements that refer to the ability of a product to maintain **healthy** structure or function" (emphasis added).[12]

The preamble to this final rule states, for example: "'Maintains healthy lung function,' alone, however, would be an acceptable structure/function claim." Other examples provided in the preamble include: "FDA agrees that 'supports a normal, healthy attitude during PMS' [is an] … appropriate structure/function claim[s]"; and, "… [A] dietary supplement could be called 'HeartTabs' if its claim was 'to maintain healthy circulation,' or some other role related to the structure or function of the heart that did not imply treatment or prevention of disease."[13]

AHPA notes that FDA first promulgated a nutrient content claim regulation for "healthy" in 1994 (i.e., before the 2000 rulemaking in which the Agency promulgated 21 C.F.R. §

[10] 21 U.S.C. § 343(r)(6).

[11] Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. Final Rule, 65 Fed. Reg. 1,000 (Jan. 6, 2000).

[12] 21 C.F.R. § 101.93.

[13] 65 Fed. Reg. at 1,018.

101.93). FDA's 2000 preamble statements regarding appropriate dietary supplement claims made pursuant to 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93 that contain the word "healthy" thus suggest that the Agency then understood that use of this term in such claims did not separately trigger the requirements of FDA's "healthy" nutrient content claim regulation. Accordingly, such lawful claims for dietary supplements may make use of the term "healthy," including when describing the supportive effect of a product, nutrient, or other dietary ingredient on a particular structure or function of the body or when making a general claim of well-being, a concept distinct from a nutrient content claim.

However, the Proposed Rule appears at best unclear whether a dietary supplement that does not meet the requirements under the Proposed Rule to bear a "healthy" claim may still bear the word "healthy" as part of an otherwise lawful claim. To fail to clarify this point would directly contradict previous FDA statements on use of the term "healthy" in lawful dietary supplement claims or otherwise when such claims relate to a product's ability to maintain a healthy structure or function. Any resultant confusion could also lead to civil litigation targeting dietary supplement labels and labeling that use the term "healthy," or that relate to healthy structure or function, in otherwise lawful claims. Revising the Proposed Rule to exclude dietary supplements would resolve this issue.

For the above reasons, AHPA requests that FDA add dietary supplements as a category of products generally allowed to make "healthy" claims in a new paragraph 101.65(d)(3)(vii) of the Proposed Rule, and elsewhere in the rule as appropriate.

II. In the alternative, FDA should revise the Proposed Rule so that the food group equivalent requirements do not apply to dietary supplements

If FDA chooses to reject the above proposal and does not exclude dietary supplements from the Proposed Rule, then FDA should revise the Proposed Rule to exempt dietary supplements from the food group equivalence requirements. As explained above, use of dietary supplements contributes to creating and maintaining a healthy dietary practice, particularly with regard to nutrients that consumers may not obtain in sufficient amounts from their consumption of conventional foods. However, imposing the food group equivalence requirements in the Proposed Rule on dietary supplements effectively prohibits most dietary supplements from bearing a "healthy" claim because most dietary supplements will not meet the food group equivalence

requirements, despite the fact that dietary supplements can promote a healthy dietary pattern.

Indeed, the Proposed Rule already excludes certain oils from the food group equivalence requirements, recognizing that consuming certain oils can contribute to a healthy dietary pattern because they are associated with positive health outcomes and provide essential fatty acids.[14] Similarly, dietary supplements are part of a healthy dietary pattern because they are associated with positive health outcomes and provide essential nutrients, including in some cases the same essential fatty acids found in oils exempted from the food group equivalence requirements under the Proposed Rule.

As a result, FDA should revise the Proposed Rule to exclude dietary supplements from the food group equivalence requirements.

III. In the alternative, FDA should revise the Proposed Rule to allow "healthy" claims on dietary supplements that contain vitamins and minerals, including nutrients of public health concern

If FDA chooses to reject the above proposals and does not revise the Proposed Rule to either exclude dietary supplements or exempt dietary supplements from the food group equivalence requirements, FDA should revise the Proposed Rule to permit dietary supplements to bear a "healthy" claim when they assist consumers in meeting intake recommendations for vitamins and minerals listed in 21 C.F.R. § 101.9(c)(8)(iv) that (a) do not also include sodium, added sugar, or saturated fats and (b) provide at least 10% of the Reference Daily Intake (RDI) or Daily Value (DV) per Reference Amount Customarily Consumed (RACC).

The Dietary Guidelines operate from an underlying assumption that Americans should meet their nutrient requirements primarily from consumption of conventional foods. However, the Proposed Rule and the Dietary Guidelines also identify calcium, potassium, dietary fiber, and vitamin D as nutrients of public health concern across the population and iron as a nutrient of public health concern for certain population groups.[15] In addition, the Scientific Report of the Dietary Guidelines Advisory Committee 2020 indicates that Americans (age 1 and older) under consume a host of

[14] 87 Fed. Reg. at 59,189.

[15] 87 Fed. Reg. at 59,173; Dietary Guidelines, at 36.

other essential vitamins, minerals, and food components relative to the Estimated Average Requirement or Adequate Intake of these; the "shortfall" nutrients not separately addressed as nutrients of public health concern include vitamins A, C, E and K as well as magnesium and choline.[16] As indicated above, the Dietary Guidelines specifically state that "dietary supplements may be useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts."[17] Dietary supplements thus help consumers maintain healthy dietary practices due to their nutrient content, particularly when they help ensure that Americans obtain recommended amounts of nutrients that they do not obtain in sufficient amounts from conventional food sources.

For this reason, AHPA requests that FDA modify the Proposed Rule to permit use of "healthy" claims for those dietary supplements that serve as sources of nutrients identified by federal regulation as essential in human nutrition, in sufficient quantities to address insufficient dietary intake from conventional foods.

IV. FDA should revise the Proposed Rule to clarify the scope of claims affected by the rule

As explained above, restricting "healthy" on dietary supplement labels and labeling would create confusion regarding the use of otherwise lawful claims on dietary supplements that include the word "healthy" as part of the claim or otherwise relate to a healthy structure or function. Regardless of whether FDA declines to exclude dietary supplements from the Proposed Rule or exempt them from the food group equivalent requirements, FDA should revise the rule and associated communications to clarify that the framework articulated in revised 21 C.F.R. § 101.65(d)(2) does not restrict use of the term "healthy" in the context of other lawful product claims.

FDA can and should accomplish this within the regulation by the addition of a new subparagraph at current proposed 21 C.F.R. § 101.65(d)(4) that states: "This section does not address the use of the term 'healthy' and related terms when used as part of a claim other than an implied nutrient content claim, including a statement subject to 21 C.F.R. § 101.93 or any successor regulation."

[16] Dietary Guidelines Advisory Committee. 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.

[17] Dietary Guidelines, at 36.

V. FDA should not reduce sodium limits applicable to "healthy" claims

In the Proposed Rule, FDA seeks comment on its proposal to lower the limit for sodium for many food categories from amounts generally near 20% of the DV per RACC to 10% of the DV per RACC. This reduction lacks a clear basis and is contrary to previous Agency findings and regulatory activity regarding sodium limits applicable to use of the term "healthy."

In its 2005 final rule regarding defined sodium limits in foods qualified for use of the term "healthy,"[18] FDA agreed to eliminate planned "second tier" sodium limits corresponding to about 15% of the DV. This decision was based in part on concerns from industry regarding the feasibility of reformulating products to meet reduced sodium levels. In the rule, FDA acknowledged the probable effect of more restrictive sodium limits to drive manufacturers to stop producing "healthy" products, having a perverse effect on the available supply of "healthy" products and on consumer dietary patterns. In response to one comment, FDA stated that it "…has enough data about the feasibility of formulating and selling 'healthy' foods at the current first-tier sodium level to be confident that retaining this level will promote the continued availability of nutritious processed foods that will assist consumers in following dietary guidelines."

FDA does not provide evidence in the Proposed Rule that would justify deviation from this position. While the Proposed Rule cites the current Dietary Guidelines to reflect an ongoing need for a reduction in public consumption of sodium, the scientifically supported intake recommendation that serves as the basis for the Dietary Guidelines recommendation has not changed. The Chronic Disease Risk Reduction Intake for sodium identified in the most recent National Academies Dietary Reference Intake (DRI)[19] is 2,300mg. This value has not changed from the Upper Limit value established by the prior DRI in 2005,[20] which is also the same limit used in rulemaking to develop the sodium limit currently in effect for "healthy" claims.

[18] 70 Fed. Reg. at 56,828.

[19] Dietary Reference Intakes for Sodium and Potassium. National Academies of Sciences, Engineering, and Medicine. Washington, DC: The National Academies Press (2019).

[20] Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. Institute of Medicine of the National Academies. Washington, DC: The National Academies Press, (2005).

A 2021 review published in *Nutrients*[21] examined whether advice to consume low amounts of sodium is supported by robust evidence. The authors concluded, "Most Americans (i.e., about four out of five people) have sodium intakes below 5 g/day, and in these individuals there is little evidence that lowering sodium will reduce cardiovascular events or death. Therefore, efforts to reduce sodium intake in entire populations cannot be justified." In supporting this conclusion, the authors asserted that "most people around the world consume a moderate range of dietary sodium (3 to 5 g/day), that this level of intake is associated with the lowest risk of cardiovascular risk," and that "cardiovascular disease risk increases when sodium intakes [sic] exceeds 5 g/day or is below 3 g/day." In discussing the policy ramifications of identifying such a range of healthy consumption, the review further states, "The Dietary Guidelines Advisory Committee (DGAC) classifies sodium as a 'nutrient of concern', based on the belief that Americans consume an excessive amount. …The DGAC recommends that sodium intake among adults should be no more than 2.4 g/day, despite a lack of evidence showing that these amounts are effective and safe, compared to the average (moderate) intake range." The authors further stated that "recommendations to reduce sodium intake in whole populations to low levels is premature."

Much like the evidence regarding sodium levels, the circumstances justifying a lower limit for sodium in "healthy" foods have not changed. While the Proposed Rule asserts that consumer demand for reduced sodium has been met by technological progress in product reformulation, the cited example does not fully support this claim. The conference report cited in the Proposed Rule to assert that industry technology has advanced in product reformulation to reduce sodium levels[22] includes statements from numerous industry stakeholders regarding the ongoing difficulties of reduced sodium product formulation as well as problems of customer perception regarding products labeled to indicate reduced sodium levels. This equivocal evidence does not justify a further reduction in overall target levels, nor does it address the underlying concerns regarding consumer preference and potential restricted access to "healthy" products that served as the basis for the 2005 finding. Similarly, partial industry adoption of

[21] Mente A, O'Donnell M, Yusuf S. Sodium Intake and Health: What Should We Recommend Based on the Current Evidence? *Nutrients*. 2021 Sep 16; 13(9):3232.

[22] Antman, E.M., L.J. Appel, D. Balentines, R.K. Johnson, et al. "Stakeholder Discussion to Reduce Population-Wide Sodium Intake and Decrease Sodium in the Food Supply: A Conference Report from the American Heart Association Sodium Conference 2013 Planning Group." *Circulation*. 2014 Jun 24;129(25).

short-term voluntary sodium reduction guidelines does not provide a specific basis for a further reduction in sodium limits, particularly in excess of a target previously found infeasible.

As a result, FDA should not reduce the sodium limits applicable to use of "healthy" implied nutrient content claims in the Proposed Rule from currently established levels.

VI. Unsweetened coffees and teas should be permitted to bear "healthy" claims

The Proposed Rule requests comment on the eligibility of calorie-free teas to bear the "healthy" claim. In line with its prior comments,[23] AHPA suggests that FDA expand the scope of proposed revised 21 C.F.R. § 101.65(d)(3)(vi) to permit the use of "healthy" claims on unsweetened coffees and teas, including black, green, and herbal teas.

Americans increasingly consume teas without added caloric sweeteners, and the Dietary Guidelines recognize that a healthy dietary pattern can include drinking unsweetened teas.[24]. A wide number of coffee products are similarly sold and consumed without added sugars. Expanding the scope of the current proposed paragraph to include noncaloric beverages commonly in use (like coffees and teas) would have the net effect of ensuring that the term "healthy" more fully reflects nutritional evidence. It may also increase the likelihood of adoption of healthy consumption behaviors by consumers who might prefer drinking unsweetened coffees or teas and disfavor unflavored water. For such consumers, these unsweetened plant-based drinks serve as a healthy substitute for caloric or sugar-sweetened beverages, and the ability of marketers to use "healthy" to promote unsweetened coffees and teas might encourage such consumers to consume them over caloric or sugar-sweetened beverages. Additionally, the ability to use a "healthy" claim would incentivize companies that market coffees and teas to formulate and offer consumers additional products intended to be consumed without sweeteners.

VII. Herbs and spices should be permitted to bear "healthy" claims

AHPA also encourages FDA to permit the use of "healthy" claims on products consisting of single or mixed herbs and spices that do not include sodium, added

[23] Comments of the American Herbal Products Association on FDA's Request for Comments on Use of the Term "Healthy" in Labeling of Human Food Products (April 26, 2017).

[24] Dietary Guidelines, at 35.

sugars, or saturated fats in any form (including powdered, liquid, granulated, or whole forms), such as those used in flavoring home-cooked meals and dishes. The Dietary Guidelines place a particular emphasis on the ease of adopting healthy dietary practices, in part through addressing and acknowledging the role of traditional foodways in achieving healthy nutritional intake. Regarding the prevalence of sodium in the American diet, the Dietary Guidelines recommend that consumers implement "multiple strategies . . . to reduce sodium intake," including advising that "flavoring foods with herbs and spices instead of salt based on personal and cultural foodways" can reduce sodium intake to recommended levels.[25] Allowing herbs and spices (or mixes thereof) to bear a "healthy" claim would encourage consumers to use these herbs and spices over seasonings and sauces that contain elevated levels of sodium, added sugar, or saturated fat.

This is particularly important given that the Proposed Rule and the Dietary Guidelines encourage increased consumption of vegetables and, as noted by the Dietary Guidelines, most consumers prepare vegetables "in forms with additional sodium either from salt added in cooking or added sauces such as soy sauce or bottled stir-fry sauces."[26] As a result, FDA regulations should encourage consumers to increase consumption of vegetables and other nutrient-dense foods while at the same time encouraging a shift towards seasonings that do not add sodium to the American diet. In addition, the ability to use a "healthy" claim would also incentivize companies to formulate and offer consumers additional herb and spice seasoning products.

Herb and spice products that do not include added sugar, sodium or saturated fats are unlikely to meet food group equivalent criteria for the use of "healthy" claims as currently proposed. This limitation would drive consumption toward less healthy flavorings and away from traditional foodways.

For the above reasons, AHPA requests that FDA add herb and spice products that do not contain sodium, added sugar, or saturated fats as a category of products generally allowed to bear "healthy" claims in a new subparagraph 101.65(d)(3)(viii) of the Proposed Rule and elsewhere as appropriate.

[25] Dietary Guidelines, at 46.

[26] Dietary Guidelines, at 32.

VIII. Dried vegetables should be considered as the sourced amount of whole vegetables for the purpose of calculating food group equivalents

In the Proposed Rule, FDA invites comments on whether the Agency should consider vegetable powders to be vegetables for the purpose of calculating food group equivalents. In raising this question, the Proposed Rule asserts that powders "could be produced or used in a way that modifies the whole vegetable to an extent that [it] removes some essential characteristics that are beneficial when consuming the whole vegetable, which could impact nutrient content."[27] By contrast, FDA "considers concentrated vegetable purees and vegetable pastes to be vegetables for the purpose of calculating food group equivalents since these products are essentially whole vegetables that have been processed to change the physical form of the vegetable to remove moisture."[28] Across all such form conversions, no evidentiary basis is provided to justify the view that a product that has been converted into another form to remove moisture has a different nutrient content compared with the source amount of whole fruit or vegetables.

AHPA requests instead that, absent evidence that a specific drying conversion action will reduce its nutrient content, manufacturers of fruit or vegetable products in any dried form (including powders) should be able to rely upon the source amount of material as the basis for the food group equivalent for the purpose of determining qualification for the use of "healthy" claims.

IX. Marketers of products lawfully bearing "healthy" claims that are already in commerce at the time of the compliance date should not need to recall such products.

FDA should clearly state in any final rule that, during the 3-year compliance period, the term "healthy" may continue to be used consistent with the existing regulation and enforcement discretion policy. Additionally, to avoid wastage associated with relabeling of existing stocks and to minimize potential market withdrawals, FDA should also state that products compliantly bearing "healthy" claims under the existing regulation and enforcement discretion policy that are already in commerce at the time of the compliance date may continue to be sold and shipped in commerce without FDA objection or enforcement.

[27] Proposed Rule, at 59,185.

[28] *Ibid.*

Summary

AHPA greatly appreciates the opportunity to present comments on the proposed regulation of "healthy" label claims. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,

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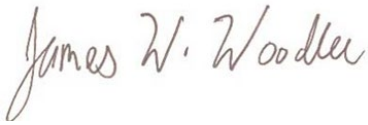

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