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COURTING CONFLICT:
HOW A NINTH CIRCUIT PREEMPTION DECISION UNDERMINES FDA ENFORCEMENT DISCRETION

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COURTING CONFLICT:
HOW A NINTH CIRCUIT PREEMPTION DECISION UNDERMINES FDA ENFORCEMENT DISCRETION

The U.S. Court of Appeals for the Ninth Circuit, in *Reid v. Johnson & Johnson*, ruled earlier this year on the appeal of one of the many state-law-based consumer class actions against food companies related to food labeling.[1] The Ninth Circuit reversed a district court decision that the state-law suit was preempted by a 2003 Food and Drug Administration ("FDA") letter of enforcement discretion that expanded a health claim for foods containing phytosterols. That letter allowed manufacturers to make health claims for a wider range of phytosterol-containing foods until FDA completes a rulemaking through the issuance of a final regulation. The district court suggested that Reid's challenge "essentially ask[s] the [c]ourt to rule on issues that the FDA has not yet finalized and seeks to impose a different, outdated interim rule requirement for [Benecol] . . . from that set forth in the 2003 FDA [l]etter."[2] The district court observed, "[F]ederal agency action short of formal notice and comment rulemaking can preempt state law."[3]

This WLF WORKING PAPER focuses on the Ninth Circuit's refusal to accept Benecol's compliance with the labeling requirements outlined in the 2003 letter as an

[1] 780 F.3d 952, at 955-956 (9th Cir. 2015).

[2] 2012 WL 4108114, at *9 (Sept. 18, 2012).

[3] *Id.* (citing *Holk v. Snapple Bev. Corp.*, 575 F.3d 329 (3d Cir. 2009) and *Geier v. Am. Honda*, 539 U.S. 861 (2000)).

adequate basis for preemption. The Ninth Circuit, in failing to grant the letter preemptive effect, risks impeding the flow of truthful health claims, as well as other similar types of claims the approval of which Congress has entrusted solely to FDA.[4]

I. THE FDA ADMINISTRATIVE RECORD CONCERNING THE CHALLENGED HEALTH CLAIM

The Nutritional Labeling and Education Act of 1990 ("NLEA") amended the Federal Food, Drug and Cosmetic Act ("FDCA") to establish, through a set of express federal preemption provisions, uniform food-labeling requirements.[5] The uniform requirements, added by the NLEA, include provisions that regulate the conditions under which health claims, including the claim at issue in *Reid*, may be expressed.[6]

FDA first allowed use of health claims associating phytosterols and reduced risk of heart disease under an interim final rule ("IFR"), which is still in effect.[7] Under the IFR, food manufacturers are permitted to market foods containing the requisite amounts of phytosterols with health claims that characterize the relationship

[4]Following the Ninth Circuit's decision, the parties reached a settlement, and the court granted dismissal. *See* Order, *Reid v. Johnson & Johnson*, No. 11cv1310 L (BLM) (July 10, 2015).

[5]Pub. L. No. 101—535, 104 Stat. 2353 (1990).

[6]*See* 21 U.S.C. § 343-1(a)(5) (providing that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement respecting any claim of the type described in [21 U.S.C. § 343(r)(1)] made in the label or labeling of food that is not identical to the requirement of section [21 U.S.C. § 343(r)] . . ."); *see also* 21 U.S.C. § 343(r)(1) (prohibiting the use of a health claim in the label or labeling of food which "expressly or by implication" "characterizes the relationship of any nutrient . . . to a disease or a health –related condition" [*i.e.*, "health claim"] unless the claim is used in accordance with conditions specified by FDA).

[7]*See* 65 Fed. Reg. 54,686 (Sept. 8, 2000); 21 C.F.R. § 100.83.

between phytosterols and the reduced risk of heart disease.[8] Manufacturers also have the option to state that these benefits are linked to the cholesterol-lowering benefits of plant sterol/stanol esters.[9] After FDA issued the IFR, Cargill Health and Food Technologies, which is a leading supplier of phytosterol ingredients for food companies, submitted a letter to FDA requesting that the agency exercise enforcement discretion to permit a broader range of foods to be marketed with the health claim until such time as the agency had the opportunity to complete its rulemaking through the issuance of a final rule.[10] The Cargill letter referenced scientific evidence suggesting that the nutritional criteria a food must satisfy to qualify for the health claim under the IFR were too restrictive, given that heart-disease-reduction benefits were also linked to "free forms" of phytosterols (*e.g.*, sitosterol, campesterol, stigmasterol, sitostanol, and capestanol) and to lower phytosterol levels than those specified in FDA's IFR.

In FDA's promptly issued response letter to Cargill, the agency acknowledged that the nutritional criteria for the health claim were too restrictive, noting that the IFR allowed the health claim to be used only for certain types of phytosterols merely

[8]21 C.F.R. § 100.83(c)(2). The rule requires a product bearing the claim to contain at least 0.65 grams of plant sterol esters or 1.7 grams of plant stanol esters.

[9]21 C.F.R. § 101.83(d)(2) (permitting health claims to disclose that "the relationship between intake of [plant sterol or stanol esters] and reduced risk of heart disease is through the intermediate link of 'blood cholesterol' or 'blood total and LDL cholesterol.'").

[10]*See* Letter from Christine L. Taylor Ph.D., Director of the Office of Nutritional Products, Labeling and Dietary Supplements (CFSAN/FDA) to Fred L. Shinnick, Ph.D., Cargill Health and Food Technologies (February 14, 2003) (responding to and discussing the contents of the Cargill letter).

because these nutrients were the focus of two previously filed health-claim petitions to which FDA's rulemaking was designed to respond. The FDA letter further stated that "substantial additional scientific evidence regarding the cholesterol-lowering efficacy of phytosterols" had subsequently come to the agency's attention and that public "comments and supporting scientific evidence now suggest that currently available scientific support extends to a broader range of phytosterol substances."[11] In addition, the FDA letter confirmed that the agency had raised no objection to voluntary notifications that it had already received regarding the "generally recognized as safe" (GRAS) determinations for various phytosterols at levels that would be necessary to justify use of the health claim. The letter emphasized that completing the rulemaking through the issuance of the final rule was a high priority for the agency, and "[p]ending completion of the final rule, FDA believes that it would be appropriate to consider the exercise of enforcement discretion with regard to use of the health claim on a wider range of foods."[12]

Despite the strong commitment expressed in the 2003 FDA letter to issuing the final health claim regulation, the agency has not yet done so, and food

[11] *Ibid.*

[12] *Ibid* (stating that the agency will consider exercising enforcement discretion with regard to the use of a claim about reduced risk of coronary heart disease in the labeling of a phytosterol-containing food, including foods other than those that qualify under the interim final rule, "if" the food meets nutritional criteria of the kind proposed by Cargill, including "(1) the food contains at least 400 mg per reference amount customarily consumed (RACC) of phytosterols; and (2) mixtures of phytosterol substances (*i.e.*, mixtures of sterols and stanols) [in the food] contain at least 80 percent beta-sitosterol, campesterol, stigmasterol, sitostanol, and campestanol (combined weight)").

manufacturers have continued to rely on the agency's policy to permit health claims for foods that meet the nutritional criteria specified in the 2003 FDA letter. In 2012, FDA reaffirmed its position on the 2003 letter, stating that it would "continue to extend [its] consideration of the exercise of enforcement discretion for the labeling of foods, including dietary supplements bearing a health claim regarding phytosterols and risk of [coronary heart disease] consistent with the 2003 letter, until publication of [a] final rule."[13]

II. THE NINTH CIRCUIT'S REJECTION OF PREEMPTION

The plaintiffs in *Reid* alleged that McNeil violated various state consumer laws with claims that the phytosterols in its Benecol products help lower cholesterol.[14] Because its Benecol products met the nutritional criteria specified in the 2003 FDA letter, McNeil argued that the plaintiffs' state-law-based allegations were preempted. The Ninth Circuit rejected McNeil's preemption arguments, although it agreed that McNeil's claims met the requirements of the 2003 FDA letter.[15]

The Ninth Circuit first acknowledged that the "Supremacy Clause gives federal authorities the power to preempt state law by declaring that the 'Constitution and

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[13]77 Fed. Reg. 9,842, 9,844 (Feb. 21, 2012). In 2010, FDA issued a proposed rule intended to supplant both the previous interim final rule and the 2003 letter. *Ibid.* However, after commenters to the proposed rule raised new data and evidence in support of the 2003 letter, FDA committed to allowing claims meeting the requirements of either the 2010 proposed rule or the 2003 letter pending a new final rule. *Ibid.* It acknowledged that the new data "may be important to [its] consideration in deciding what requirements to include in the final rule." *Ibid.*

[14]*Reid*, 780 F.3d at 956.

[15]*Id.* at 963.

the Laws of the United States . . . [are] the supreme law of the land.'"[16] The court further stated that "[t]he phrase 'Laws of the United States' encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization."[17] The court reasoned that "[b]ecause the Supremacy Clause privileges only '[l]aws of the United States,' an agency pronouncement, short of a formal regulation, must have the force and effect of federal law to have preemptive force."[18] The court found that beyond the Supremacy Clause, "there is nothing to guide us in determining whether an agency action creates 'law' for [preemption] purposes."[19] In order to fill the void, the court turned to an analogous standard used in the context of the *Chevron* doctrine.

The court observed that under *Chevron*, "when an agency fills a gap in a statute that Congress explicitly or implicitly left open for that agency to fill, [the agency's] regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute."[20] It noted, however, that short of formal regulations, "only those agency pronouncements that Congress intended to carry the 'force of law' require *Chevron*-level deference," and courts determine

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[16] *Ibid.* (citing U.S. Const. art. VI, cl. 2).

[17] *Ibid.* (quoting *City of New York v. FCC*, 486 U.S. 57, 63 (1988)).

[18] *Ibid.* (citing *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 245 (3d Cir. 2008); *Wabash Valley Power Ass'n, Inc. v. Rural Electrification Admin.*, 988 F.2d 1480, 1485-1486 (7th Cir. 1993)).

[19] *Ibid.*

[20] *Ibid.*

"whether an agency spoke with such force under the standard set forth in *United States v. Mead Corp.*"[21] The Ninth Circuit reasoned that "[c]reation of federal law should demand at least the same formality for purposes of preemption as it does for purposes of *Chevron* deference."[22] The Ninth Circuit did not, however, explore exactly what the "force of law" might mean under *Mead* and cases following *Mead.* The Ninth Circuit, rather, appears to have created, in a case of first impression in the Ninth Circuit, the foundation for a new and unique "force-of-law" doctrine for preemption purposes.

The Ninth Circuit identified four reasons why FDA's 2003 letter of enforcement discretion lacks the force of law.[23] First, the court pointed to the letter's language, which states that FDA "intends to consider the exercise of enforcement discretion" in allowing the requested claims for phytosterols.[24] The court deemed this language "equivocal" and found that it was "a good indication that [FDA] did not intend to foreclose state law challenges to health claims that do not comply with existing rules."[25] The court next pointed to the surrounding statutory scheme for health claims. It noted that a statutory provision specifically enables FDA to approve health claims as interim final rules that are effective immediately—and, that FDA had used

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[21] *Id.* at 964.

[22] *Ibid.*

[23] *Id.* at 965.

[24] *Ibid* (quoting Letter from FDA to Cargill Health and Food Technologies (Feb. 14, 2003)).

[25] *Ibid.*

this provision in issuing its original phytosterols rule. According to the court, FDA's declining to use that authority again, and instead issuing the 2003 letter, "indicates that the FDA did not intend to issue a statement with the force of law that would foreclose the protections under state law food labeling and false advertising claims."[26] Third, the court considered congressional intent emanating from the regulatory scheme and found no intent to create "an unstated means of rulemaking by way of letters tentatively stating the FDA's enforcement discretion."[27] Fourth, the court considered potential implications for judicial review. It observed that "agency decisions not to take enforcement action are usually committed to agency discretion by law and thus generally not subject to judicial review under the Administrative Procedure Act."[28] It found that "[f]oreclosing challenges to, and judicial review of, the FDA's health claim approvals [made via letter] likely would not serve Congress's goals in the [Food Drug and Cosmetic Act] of increasing protections of public health and safety."[29]

The Ninth Circuit, in sum, focused on the language of the letter being "equivocal" and "tentative," an interpretation of Congressional intent based on the surrounding regulatory scheme, and potential practical implications for judicial review. This analysis, unfortunately, does not acknowledge that FDA's exercise of

[26] *Ibid.*

[27] *Ibid.*

[28] *Ibid.*

[29] *Ibid.*

enforcement discretion to permit well-supported claims is a practical response to cumbersome rulemaking procedures that can function to ban truthful claims until authorized by regulation. By exercising its enforcement discretion in allowing additional phytosterols claims under the 2003 letter, FDA balanced the burdens of rulemaking against First Amendment commercial speech considerations and the public-health benefit of disseminating valid health information.

III. THE OUTLOOK FOR FOOD AND DIETARY SUPPLEMENTS MARKETED IN RELIANCE ON FDA ENFORCEMENT DISCRETION

The Ninth Circuit's holding in *Reid* poses a new threat for commercial claims made in reliance upon FDA enforcement discretion. Of particular note are qualified health claims, which are always authorized solely on the basis of enforcement discretion letters, rather than explicit regulations. Assessing the potential impact of *Reid* on qualified health claims will help highlight the First Amendment issues the case implicates.

Unlike health claims, which the NLEA expressly authorized, qualified health claims came about through litigation in the D.C. Circuit. Prior to the litigation, FDA had rejected any proposed health claim that lacked "significant scientific agreement." The plaintiffs, who were dietary supplement sellers, argued that this approach violated the First Amendment given that claims could accurately and understandably disclose the level of scientific support, even if the level of support did not rise to

significant scientific agreement.[30] The D.C. Circuit agreed with the plaintiffs,[31] and FDA subsequently implemented a system to review what came to be called "qualified health claims." Under the current system, if FDA decides to allow a qualified health claim, it issues a letter of enforcement discretion. Since 2000, FDA has approved 18 different qualified health claims under this system.[32]

Following *Reid*, it appears that any court in the Ninth Circuit could easily find no preemptive effect for qualified-health-claim letters despite the court-mandated nature—and First Amendment underpinnings—of the qualified-health-claims regime. The routine language of qualified-health-claim letters is similar to the 2003 letter at issue in *Reid.* As an example, the following is from FDA's most recent letter allowing a new qualified health claim:

> This letter sets forth the basis of FDA's determination that the current scientific evidence regarding the relationship between psyllium husk and type 2 diabetes is appropriate for consideration of a qualified health claim on conventional foods and dietary supplements. In addition, this letter sets forth . . . qualified health claim language for which FDA intends to exercise enforcement discretion. This letter also sets forth the factors that FDA intends to consider in the exercise of its enforcement discretion . . .[33]

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[30]*Pearson v. Shalala*, 164 F.3d 650, 654-655 (1999).

[31]*Id.* at 659. The court also held that FDA violated the Administrative Procedure Act by failing to define "significant scientific agreement." *Id.* at 660-661.

[32]FDA, Summary of Qualified Health Claims Subject to Enforcement Discretion (last updated Dec. 14, 2014), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073992.htm.

[33]FDA Qualified Health Claim Letter to Procter & Gamble Co., Docket No. FDA-2013-Q-0167, at 2 (June 23, 2014).

The focus on FDA's "considering" the claim and "intend[ing] to exercise[] enforcement discretion" echoes the language with which the Ninth Circuit took issue in *Reid*. A judge in the Ninth Circuit, thus, could easily find qualified-health-claim letters to be "equivocal" as the letter at issue in *Reid*. Similarly, the potential for a lack of judicial review would be as present as it was for the letter at issue in *Reid* given that, like that letter, qualified-health-claims letters represent "agency decisions not to take enforcement action." A court could likewise find—as it did in *Reid*—no intent by Congress to create "an unstated means of rulemaking by way of letters tentatively stating the FDA's enforcement discretion."

Apart from qualified health claims, the *Reid* decision could have similar effects on a wide variety of other claims and practices allowed on a temporary basis in reliance on FDA discretion. For instance, when FDA this year revoked the GRAS status of any uses of partially-hydrogenated oils, it provided a compliance date of June 18, 2018.[34] This compliance date allows companies three years in which to reformulate products before FDA will take enforcement action. This grace period, however, is based solely on FDA's exercise of enforcement discretion, and the protections of the grace period will be significantly curtailed if FDA's decision to exercise enforcement discretion will not be granted preemptive effect by courts hearing class actions, or other actions by private parties, based on state advertising and labeling laws.

[34] 80 Fed. Reg. 34,650 (June 17, 2015).

IV. WHY *REID* MAY PROVE INFLUENTIAL

Reid appears to be the only case to date involving the preemptive effect of an FDA letter of enforcement discretion. However, in *Reid*, the Ninth Circuit noted that it was following the Third Circuit in requiring that non-binding agency pronouncements have the "force of law" under *Mead* in order to be given preemptive effect.[35] In *Fellner v. Tri-Union Seafoods, LLC*, the Third Circuit held that an FDA Compliance Policy Guide, consumer advisory, and "backgrounder" about methylmercury in tuna lacked the "force of law" and therefore did not preempt a state-law action against a seafood company for failing to warn consumers about the risks of methylmercury in its tuna products.[36] In another case, *Holk v. Snapple Beverage Corp.*, the Third Circuit refused to grant preemptive effect to either FDA's policy on "natural" claims for foods or warning letters based on that policy.[37] The court thereby allowed a plaintiff to proceed with a state-law challenge to "all natural" claims used in the marketing of Snapple beverages.[38] No other federal circuit courts have considered the preemptive effect of similar non-binding agency

[35]780 F.3d at 964.

[36]539 F.3d at 251-254, 241.

[37]575 F.3d 329, 342 (3d Cir. 2009).

[38]*Id.* at 332. *Fellner* and *Holk* differ somewhat from *Reid* in that the courts focused on the "fairness and deliberation" underlying the agency pronouncements, rather than the language of the agency pronouncement and the surrounding legal framework.

pronouncements.[39]

District courts in the Third, Fourth, Fifth, Ninth, and Eleventh circuits have followed *Fellner* and *Holk* and denied preemptive effect for non-binding agency pronouncements.[40] Only two district courts appear to have reached decisions that are arguably contrary in giving controlling weight to agency guidance documents.[41] In *Gallagher v. Bayer AG*, plaintiffs alleged state-law causes of action based on Bayer's purported violations of FDA's rule that any disease claims for dietary supplements must be preapproved.[42] Bayer used certain claims, including "supports immunity" and "supports heart health," in the marketing of its multivitamins.[43] Based on specific examples in FDA guidance allowing similar claims (*e.g.*, "supports the immune system") without preapproval, the court held that the plaintiff's causes of action

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[39]Courts have granted controlling effect to Office of Thrift Supervision opinion letters interpreting the agency's preemption regulations. *See, e.g.*, *SPGGC, LLC v. Ayotte*, 488 F.3d 525, 536 (1st Cir. 2007); *Cedeno v. IndyMac Bancorp, Inc.*, 2008 WL 3992304, at *6 (S.D.N.Y. Aug. 26, 2008); *State Farm Bank, F.S.B. v. Burke*, 445 F. Supp. 2d 207, 219-220 (D. Conn. 2006).

[40]*See, e.g.*, *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 413 (S.D.N.Y. 2011) (refusing to grant preemptive effect to same documents at issue in *Fellner*); *In re Frito-Lay North America, Inc. All Natural Litigation*, 2013 WL 4647512, at *10 (E.D.N.Y. Aug. 29, 2013) (refusing to grant preemptive effect to FDA's policy on "natural" claims); *Mun. Ass'n v. Serv. Ins. Co.*, 786 F. Supp. 2d 1031, 1047-1048 (2011), rev'd on other grounds, 709 F.3d 276 (4th Cir. 2013); *Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 285 (S.D.N.Y. 2014) (refusing, in consumer action against milk product, to grant preemptive effect to compliance guides on carrots and peas and jellies and rule on bottled water); *Gedalia v. Whole Foods Market*, 53 F. Supp. 943, 949 (S.D. Tex. 2014); *see also Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 29 1028,1033 (N.D. Cal. 2009) (refusing to grant preemptive effect to FDA policy on "natural" claims); *Hitt v. Arizona Beverage Co.*, 2009 WL 449190, at *5 (S.D. Cal. Feb. 4, 2009).

[41]*See Gallagher v. Bayer AG*, 2015 U.S. Dist. LEXIS 29326 (N.D. Cal. Mar. 10, 2015); *In re Pepsico, Inc.*, 588 F. Supp. 2d 527, 537 (2008).

[42]2015 U.S. Dist. LEXIS 29326, at *3-4.

[43]*Ibid.*

were preempted.[44] In another case consolidated in the Southern District of New York, plaintiffs alleged that mountain scenes on bottles of water sold by PepsiCo, Inc. deceived consumers regarding the source of water, which was a municipal water system.[45] Plaintiffs sought relief under state consumer-protection laws. The court held that FDA's standard of identity for bottled water preempted the suit.[46] The court pointed specifically to statements in FDA's Final Rule notice for the standard of identity. The statements clarified that FDA would not consider imagery of "a country setting," including lakes or ponds, to be deceptive as long as water from a municipal source was purified.[47] PepsiCo's bottled water was purified.

Prior to *Reid*, the Ninth Circuit had allowed preemptive effect for a non-binding FDA guidance document in a putative class action against the makers of a contact lens solution.[48] While a petition for rehearing was pending in the case, however, the parties reached a settlement, and the Ninth Circuit vacated its decision.

At least one other case, beside *Reid*, has involved McNeil's cholesterol-lowering claims for Benecol.[49] In that case, the Third Circuit held that the IFR preempted the state law claims; the court, however, effectively dodged the issue of

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[44] *Id.* at *6, *21.

[45] 588 F. Supp. 2d at 530-531.

[46] *Id.* at 537.

[47] *Ibid.*

[48] *Degelmann v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 841-842 (9th Cir. 2011), vacated, 699 F.3d 1103 (9th Cir. 2011).

[49] *Young v. Johnson & Johnson*, 525 Fed. Appx. 179, 2013 WL 1911177 (3d Cir. May 9, 2013).

the preemptive effect of the 2003 letter. As in *Reid*, the Benecol product included an amount of phytosterols that was consistent with the 2003 letter, but not the IFR.[50] The court found that the plaintiff "d[id] not appear to challenge Benecol's ability to make cholesterol-lowering claims based on the amount of plant stanol esters."[51] Thus, it did not rule on the preemptive effect of the letter apart from the rule.

At this point, with precedential support from *Fellner* and *Holk*, and only two district court cases arguably running counter, *Reid* unfortunately appears poised to influence federal courts beyond the Ninth Circuit.

CONCLUSION

Preemption cases involving challenges to labeling or advertising statements uniquely implicate First Amendment concerns, including both the interests of companies to engage in commercial speech and the interests of consumers to receive truthful, accurate information that may impact their health and well-being. Statements of FDA enforcement discretion designed to allow a broader range of truthful claims in the marketplace and enable the agency to implement the FDCA in ways that minimize the risk of First Amendment violations. These statements are unlikely to be given the weight they deserve when preemption is considered apart from the statutory and First Amendment standards that govern state-law labeling. The Ninth Circuit's decision in *Reid* sets a rigid precedent that risks allowing state-law

[50] *Id.* at 181.

[51] *Id.* at 184 n.6.

labeling claims to undermine Congress's mandate to FDA to ensure truthfulness and uniformity in food and dietary supplement labeling.