National Milk Producers Federation

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The National Milk Producers Federation ("NMPF") appreciates the opportunity to meet with the Office of Information and Regulatory Affairs ("OIRA") on May 16 to discuss the Food & Drug Administration's ("FDA") recently announced draft guidance: Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry ("the Draft Guidance"). NMPF develops and carries out policies that advance the well-being of dairy producers, the cooperatives they own, and the consuming public.

NMPF urges OIRA to return to FDA any draft guidance that seeks to amend existing law and regulations through guidance. As discussed in detail in NMPF's citizen petition to FDA,[1] longstanding FDA regulations and regulatory policies prescribe naming requirements for food products, including plant-based milk alternatives. Specifically, the federal Food, Drug & Cosmetic Act ("FDCA") and related FDA regulations prohibit labeling that falsely implies that the non-dairy substitutes are equivalent to and interchangeable with standardized dairy foods and that fails to disclose the material facts concerning how these non-dairy substitutes differ from standardized dairy foods. Any guidance document that suggests that non-dairy substitutes may be labeled with reference to a standardized dairy food such as "milk" without also being labeled as "imitation' or "substitute" runs contrary to longstanding law and regulations. Because FDA lacks the authority to amend existing law and regulations through guidance issued outside of the notice and comment rulemaking process, NMPF urges OIRA to return any such guidance to FDA.

I. Background

In February 2019, the NMPF submitted a citizen petition under Sections 201, 201a, 201c, 301, 401, 402, 403 and 701 of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act") to request that the Commissioner take certain actions to:

1) enforce existing "imitation" labeling requirements against nutritionally inferior non-dairy substitutes for standardized dairy foods that are named and positioned as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," yet fail to provide the "imitation" disclosure statement that is required under the Act and FDA implementing regulations; and

2) amend section 101.3(e) of FDA regulations to codify in more detailed form longstanding FDA policies that permit the name of a standardized dairy food (e.g., "milk," "yogurt," "cheese," "ice cream," "butter") to be

[1] National Milk Producers Federation Citizen Petition to the Food & Drug Administration (Feb. 21, 2019), https://live-nmpf.pantheonsite.io/wp-content/uploads/2019/03/National-Milk-Producers-Federation-Citizen-Petition-and-Attachments.pdf.

used in the statement of identity of a non-dairy substitute for the standardized food only under limited and defined conditions.

As explained in the petition, these actions were – and continue to be – necessary to stem the tide of nutritionally inferior, non-dairy, plant-based foods that are being labeled and marketed in a manner that misrepresents these foods as forms of "milk," "yogurt," "cheese," "ice cream," or "butter," falsely implies that the non-dairy substitutes are equivalent to and interchangeable with standardized dairy foods, and fails to disclose the material facts concerning how these non-dairy substitutes differ from standardized dairy foods or adequately distinguish non-dairy substitutes derived from different plant sources. FDA never responded to NMPF's petition.

II. Standardized Terms in Names of Nonstandardized Products Falsely Imply Equivalence and Present Consumer and Public Health Issues

As described in detail in the petition, the use of standardized dairy terms that have been defined by law and/or FDA regulation to name standardized dairy foods for the disparate purpose of identifying a non-dairy substitute for the reference standardized dairy food completely disregards FDA requirements governing the use of a standardized term to name a nonstandardized food.[2] Such use implies a false equivalence between the respective reference standardized dairy food (*e.g.*, milk) and the non-dairy substitute that bears an identity statement that misappropriates a term from the legal name of the reference standardized food.

And while the identity statements used for such non-dairy substitutes generally include a term that refers to one or more plants from which ingredients have been derived (*e.g.*, almond, flax, hemp, oat, rice, soy), this practice does not adequately identify or describe "the basic nature of the food or its characterizing properties or ingredients," and fails to disclose the material differences that exist between the non-dairy substitute and the reference standardized dairy food, as required by the FDCA and FDA regulations. Indeed, the FDCA and FDA regulations clearly define the circumstances when a nonstandardized food can borrow from the name of a standardized food.[3] FDA repeatedly and consistently restated this position over the years based on the determination that such naming requirements were necessary to protect the consumer and public health objectives underlying FDCA's statutory authority to establish standards of identity and related food labeling requirements.

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[2] *See, e.g.*, 21 C.F.R. §§ 130.10, 101.67 and FDA's discussion of its policies in the related rulemaking records.

[3] These limited circumstances typically involve modified food that can still be "fairly described" as the standardized food, including by requiring dairy ingredients to be major ingredients of nutritionally modified foods that are identified using a standardized dairy term in the statement of identity (*e.g.*, milk, yogurt, cheese, ice cream, butter, or another standardized dairy food).

III. FDA Lacks Authority to Modify Existing Laws and Regulations Through Guidance Issued Without Notice and Comment Rulemaking

Because these requirements are grounded in decades of law and precedent but have not been recently enforced, NMPF requested in its citizen petition that FDA both: (1) enforce existing labeling requirements related to nutritionally inferior non-dairy substitutes that are labeled with reference to standardized dairy terms; and (2) amend FDA regulations to codify in more detailed form these longstanding FDA policies. FDA declined to do either and failed to respond to NMPF's petition.

In the event that FDA's Draft Guidance diverges from these established requirements, FDA would be acting in violation of precedent that prohibits federal agencies from revising or broadening existing law by way of issuing guidance without notice and comment rulemaking. For example, in *American Academy of Pediatrics v. F.D.A*., the court found that FDA violated the Administrative Procedures Act ("APA"), 5 U.S.C. § 701 *et seq*. by issuing the Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised) without following the APA's notice and comment requirements. [4]

In that case, the court determined that "an agency enforcement decision, including a refusal to take enforcement action, may be reviewed in court (1) if the agency's decision is a statement of statutory interpretation, albeit couched as an exercise of enforcement discretion; (2) if Congress indicated, such as through the language of the statute itself, that it intended to circumscribe the agency's enforcement discretion or (3) if it amounts to a rule amendment or revocation." (citations omitted). Because the Tobacco Control Act clearly delineated the pre-market review requirements for deemed products by specific dates, and because FDA's guidance modified the statutory deadlines in a manner that was binding in practice, the court determined that FDA's decision to issue guidance without notice and comment was reviewable. Moreover, because the effect of the guidance was contrary to the purpose of the Tobacco Control Act by allowing deemed products to remain on the market without premarket review longer than statutorily allowed, the court determined that FDA's action amounted to "holding in abeyance enforcement of mandatory provisions of a statute that Congress viewed as integral to address public health dangers that the agency itself acknowledges are alarming for five or more years while it tries to figure out how it will implement the

[4] *See Am. Acad. of Pediatrics v. Food & Drug Admin.,* 399 F. Supp. 3d 479 (D. Md. 2019); *see also Appalachian Power Co. v. EPA*, 341 U.S. App. D.C. 46, 208 F.3d 1015, 1028 (2000) (Petitioners challenged EPA guidance which outlined periodic monitoring of source point emissions subject to Title V of the Clean Air Act Amendments of 1990. "In sum, we are convinced that elements of the Guidance-those elements petitioners challenge—significantly broadened the 1992 rule. The more expansive reading of the rule, unveiled in the Guidance, cannot stand.")

statute, all the while affording those manufacturers responsible for the public harm a holiday from meeting the obligations of the law."[5]

The same rationale applies with respect to FDA's issuance of this Draft Guidance regarding labeling of plant-based dairy products. In 2018, FDA sought and received public comments regarding labeling of plant-based foods.[6] In that request, FDA recites the standards of identity for milk, yogurt, cheese, etc., and states that "[U]nder section 403(g) of the FD&C Act, a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulation, unless it conforms to such definition and standard."[7] FDA did not pursue notice and comment rulemaking, but instead announced in January 2022 that the Agency intended to issue draft guidance regarding labeling of plant-based dairy products by the end of December 2022.

Should the Draft Guidance articulate a position that has the practical effect of finding that nonstandardized plant-based products bearing the standardized names are not misbranded, such a position would be contrary to the FDCA and FDA regulations, and in violation of substantive and procedural safeguards imposed by the APA. NMPF urges OIRA to carefully consider the defensibility of the Draft Guidance in light of its practical and legal effect and FDA's decision not to undertake notice and comment rulemaking.

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NMPF thanks OIRA for its consideration of these important issues. We look forward to discussing them further on May 16.

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5 399 F. Supp. 3d at 493.

6 83 Fed. Reg. 49,103 (Sept. 28, 2018).

7 *Id.* at 49,104.