HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via regulations.gov

September 15, 2025

Docket Clerk
Office of Legal Policy
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, DC 20530

RE: Docket No. OLP182 - Request for Information on State Laws Having Significant Adverse Effects on the National Economy or Significant Adverse Effects on Interstate Commerce

Dear Docket Clerk,

The Healthcare Nutrition Council (HNC) is commenting on Docket No. OLP182 titled Request for Information (RFI) on State Laws Having Significant Adverse Effects on the National Economy or Significant Adverse Effects on Interstate Commerce that was posted by the U.S. Department of Justice (DOJ or Department) to the *Federal Register* on August 15, 2025. HNC represents manufacturers[1] of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods[2] and foods for special dietary use (FSDU),[3] and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access for people that require or benefit from advanced and specialized nutrition.

We acknowledge this administration's focus on public health and nutrition and we support people living healthier lives. However, we are concerned with the patchwork of state food legislation that has arisen over the last few years and has been particularly high in 2025. Namely, we have estimated over 125 bills in about 37 state legislatures that have been introduced since January 1 and that seek to require warning labels, bans, or other restrictions on a number of food ingredients. Some of these ingredients are used in medical foods, tube feeding formulas, ONS, and specialized nutrition products that are used by people (often sick people) with specific nutritional needs. Many of these ingredients have a long-standing approval by the U.S. Food and Drug Administration (FDA), have been reviewed for safety by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and are permitted for use in dozens of countries globally. While many of these bills did not proceed, we estimate about 10 have been signed by governors so far this year and will go into effect very soon. These new state laws are very disruptive to global trade and interstate commerce and go against approvals and scientific backing by FDA and several other authorities. It is for these reasons we appreciate the

[1] HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.
[2] A **medical food** as defined in section 5(b)(3) of the Orphan Drug Act. 21 USC 360ee(b)(3): "a food which is formulated to be consumed or administered **enterally** under the **supervision of a physician** and which is intended for the specific **dietary management of a disease or condition** for which **distinctive nutritional requirements**, based on recognized scientific principles, are established by **medical evaluation**."
[3] 21 CFR Part 105

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opportunity to provide comment to the Department on this RFI on state laws significantly and adversely affecting the national economy or interstate commerce along with suggested solutions that could address such effects.

There is a spectrum of conditions that are indications for certain nutrition products that could range from PN, EN, to options for oral supplementation or sole-source nutrition to meet the individual's unique needs. These products are uniquely formulated to address nutrition needs temporarily or permanently depending on the clinical situation of the person. They are designed to supplement diets or provide meal replacement for whatever reason the person cannot live with conventional foods alone. Infant formula, medical foods, and FSDU are all defined and regulated uniquely by FDA and they are different from conventional foods.

The ingredients in specialized nutrition products are reviewed by FDA for safety and tolerance and are chosen by the researchers and manufacturers based on a spectrum of conditions from food allergies to chronic disease. Some ingredients are used to maintain the integrity of vitamins and minerals in the product, keep nutrients suspended in the solution or formula, maximize nutrient delivery, and offer a solution to meet the unique nutrition requirements of the person's dietary needs. In many cases, clinical trials and studies are conducted before the products come to market. If an ingredient is not available or becomes banned, it is very difficult for manufacturers to reformulate and the process could take several years to be sure a substitute ingredient still meets the need of the intended user. Often the intended user is in a very vulnerable population, such as an infant or someone with a rare disease, where testing a new formulation would be incredibly difficult. Likewise, legislation calling for warnings of certain ingredients that may be included, and may play an important role in, a specialized nutrition product could be very confusing for patients when they have been using and trusting a product for their condition and know that it is backed by science and safety reviews by FDA. If there is a label warning and distrust, the person may no longer use the product or the manufacturer could discontinue the product to avoid using a misleading warning statement. In some cases, there are no alternative products available for the person to use. An unintended consequence of ingredient bans or warning labels could mean a specialized nutrition product is no longer available on the market and patients/consumer could be faced with severities of malnutrition.

Below are responses to the questions raised by the Department in the RFI.

Which state laws significantly burden commerce in other states and between states, thus raising costs unnecessarily and harming markets nationwide?

Texas SB25 of 2025 was passed, signed by Governor Abbott, and includes a food warning label requirement: "A food manufacturer shall ensure each food product the manufacturer offers for sale in this state includes a warning label disclosing the use of any of the following ingredients, if the United States Food and Drug Administration requires the ingredient to be named on a food label and the ingredient is used in a product intended for human consumption" and 44 ingredients are listed. The label must read "WARNING: This product contains an ingredient that is not recommended for human consumption by the appropriate authority in Australia, Canada, the European Union, or the United Kingdom." A federal preemption component is included in the new law that notes the warning label would not take effect if FDA or USDA "determines an ingredient or class of ingredients is safe for human consumption."

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Louisiana SB14 was signed by Governor Landry on June 20 as Act No. 463. Act No. 463 mandates labeling or "disclosure of harmful ingredients" which is misleading, as many of the listed ingredients are not harmful and have proof of safety reviews conducted by authorities around the world. Products containing a certain ingredient must undergo additional, burdensome labeling requirements. As stated in the Act, "The product label shall include a quick response code, or QR code, with a statement adjacent to the code that informs the consumer that additional ingredient information can be accessed by scanning the code. The QR code shall link to a web page that is under the control of the manufacturer. The web page shall contain the following disclaimer in a prominent location: 'NOTICE: This product contains [insert ingredient here]. For more information about this ingredient, including FDA approvals, click HERE.' The disclaimer shall link to the United States Food and Drug Administration's web page regarding food chemical safety."

The labeling provisions in Texas SB25 and Louisiana SB14 go beyond current labeling laws required by the U.S. Food, Drug, and Cosmetic Act (FD&C). HNC member companies comply with FDA regulations and guidance regarding Nutrition Facts labeling, ingredient statements, nutrition content, and structure/function claims. We believe consumers are already receiving accurate information about these products that comply with 403(q) (nutrition labeling) and 403(a)(1) (false and misleading). The ingredients listed in the state laws are already required by federal law to be included in the list of ingredients on the package, are approved for use in the U.S. and around the world, and have rigorous scientific backing that they are not harmful. The addition of a warning label or QR code could confuse consumers and be misleading. If these ingredients are safe and approved at the federal level, then that would include Texas and Louisiana, so the label could be misleading. The warning label (Texas) and QR code (Louisiana) raises different interstate challenges if the neighboring state does not have this disclosure. A neighboring state may consider disclosure not truthful under the Fair Packaging and Labeling Act (FPLA) regulations. The federal and state government cannot compel misleading speech under the First Amendment.

Companies trade globally and follow federal labeling laws when they import and export in order to comply in that market. Many companies cannot control for all levels of distribution including interstate commerce and online sales. For these reasons, Texas's and Louisiana's labeling laws will be treated by companies as a federal law if they want to avoid violations in the state. International and U.S.-based companies have been following the legislative actions in U.S. states legislatures and are making difficult business decisions on whether or not to sell in the market. A patchwork of state policies that contradict FDA's labeling requirements are incredibly challenging for manufacturers to understand and be in compliance with both jurisdictions.

As an industry, HNC is committed to food safety and quality, and we follow FDA's national framework of requirements for the safety of food ingredients. We support the FDA's role in actively monitoring reports of potential issues related to food additives and taking appropriate corrective measures when necessary. Further, the FDA is responsible for ensuring that all foods sold in the United States are properly labeled, including medical foods and FSDU. Additional labeling requirements, such as those included in Texas SB25 and Louisiana SB14 could negatively impact patients and potentially limit their access to these important and at times lifesaving products.

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Medical foods and FSDUs are regulated differently than other foods and beverages due to the conditions of the populations they benefit. For instance, some of these medical foods are used for patients with inborn errors of metabolism, example of a metabolic condition, that cause patients to have an altered nutrient profile. The incidence of Phenylketonuria (PKU), an inborn error of metabolism, is quite rare - 1 in 25,000 births. Medical foods are necessary to meet these patient's diet requirements, which require a carefully controlled intake of amino acids and specific medical foods. Due to the small, niche population, these specialized products are not produced as often (smaller scale production) as general food products. Therefore, additional labeling, specific to Texas and Louisiana, would place undue burden on manufacturers producing these specialized medical foods since they do not produce state-specific labeling or have state specific distribution channels. For the food industry at large, the administrative burden and additional cost for the company should be considered, especially for small and local businesses. Companies may decide to no longer sell in Texas or Louisiana in order to avoid additional labeling requirements. This could have a significant impact on the economy for jobs in sales and production and could impact availability of food in the grocery stores.

Our goal is to ensure patients and families continue to have access to affordable nutrition products that are life-sustaining and provide required nutrition to promote health and wellbeing. Ingredients are already disclosed on packaging and warning labels will unnecessarily confuse patients who are using nutrition products that may have been recommended by their healthcare provider for a specific health purpose.

These points noted above were shared multiple times with members of the Texas legislature as HNC requested exemption of medical foods and FSDU from the bill, but unfortunately this exemption was not granted. Louisiana did exempt medical foods but did not exempt FSDU.

Whether the laws identified may be preempted by existing federal authority and, if so, what authority?

The concerns described above could be addressed with federal preemption and keeping food safety authority and food labeling requirements strictly at the federal level between FDA and USDA. FDA should have preemption authority over food additives when it comes to their safety review and approved level of use. We should support a strong, singular federal food safety program. Similarly, FDA and USDA should have preemptive authority over any food and beverage labeling requirements so that states cannot mandate additional disclosures that go beyond, or are contradictory, to what is currently required by labeling laws, such as from the Nutrition Labeling and Education Act (NLEA).

A state patchwork of food labeling laws would also raise significant Interstate Commerce Clause considerations because these laws could discriminate against or excessively burden interstate commerce. Food products are not manufactured in each state in which they are sold; instead, food products are generally produced for nationwide distribution, with one uniform label. Individual state requirements for labeling foods will require significant additional resources for manufacturers and distributors, which would excessively burden interstate commerce. HNC would like clarity on how the Interstate Commerce Clause (U.S. Constitution, Article I, Section 8, Clause 3) could be applied to cases of food labeling. In the examples of Texas and Louisiana,

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differing requirements could hinder the movement of products across state borders. This is an area for DOJ to investigate.

Whether there may be federal legislative or regulatory means for addressing the state laws identified or the burdens they cause?

Federal legislation would be required to grant FDA express preemptive authority over food additive approvals and other ingredient authorizations, food labeling laws, or any other food related concerns raised by states. It is imperative that our country maintains a strong federal food policy regulatory framework and to avoid a patchwork of confusing state laws that are contradictory to each other and federal law.

Which federal agency has the subject-matter expertise to address concerns lawfully within the federal government's authority?

FDA has the scientific expertise and authority over food additive reviews and labeling compliance. However, without federal preemption, FDA currently cannot prevent states from ingredient restrictions that contradict FDA's authorities nor can they prevent certain labeling requirements enacted by states.

We appreciate your consideration of these comments. Please contact Berit Dockter MPP, RD, LD bdockter@healthcarenutrition.org if you have any questions.

Sincerely,

Carla A. Saunders

Carla Saunders
Executive Director

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