

**BEFORE THE UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION**

PETITION FOR RULEMAKING

TO PROMULGATE A REGULATORY FRAMEWORK FOR THE LABELING
OF ANIMAL-DERIVED INGREDIENTS IN FOOD PRODUCTS

September 24, 2024

SUBMITTED BY:

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CENTER FOR JEWISH FOOD ETHICS
EARTHJUSTICE
FARM FORWARD
FARMSTAND
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September 24, 2024

Xavier Becerra, Secretary
U.S. Department of Health and Human Services
200 Independence Ave S.W.
Washington, DC 20201

Robert M. Califf, Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Secretary Becerra and Commissioner Califf:

The undersigned seventeen organizations and individuals¹ submit this petition pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(e) (APA), and 21 C.F.R. § 10.30, requesting the Commissioner of Food and Drugs to issue a regulation requiring food products that contain animal-derived ingredients be labeled as such in order to properly inform and protect the millions of U.S. consumers who cannot consume animal-derived products due to medical concerns, religious and ethical restrictions, or other reasons.

A. Action Requested

The undersigned petitioners request that FDA promulgate rules governing the labeling of animal-derived ingredients. Specifically, petitioners urge the agency to require products that contain animal-derived ingredients to be labeled with a disclaimer on the product's Principal Display Panel (PDP) that states that the product contains animal-derived ingredients, identifying the species in the statement. For example: "contains (species)-derived ingredients," "contains animal-derived ingredients (species)," "contains ingredients derived from (species)," or "contains (species) ingredients." Alternatively, Petitioners request FDA to require this disclaimer on the Informational Panel alongside the ingredients list and allergen disclaimer.

B. Statement of Grounds

I. Disclosure of animal-derived ingredients is necessary to ensure compliance with the Federal Food, Drug, and Cosmetic Act.

Congress designed the Federal Food, Drug, and Cosmetic Act (FDCA) to promote public health by preventing fraudulent activity with respect to food, drugs, and other public health

¹ In addition to the undersigned organizations and academics, petitioners submit a list of 7,351 American consumers who have signed on to support this petition. *See* Ex. 1.

products.² As the agency chiefly tasked with enforcing the FDCA, FDA’s primary purpose is to safeguard and protect consumers and promote public health and safety. FDA is “responsible for assuring that foods sold in the United States are safe, wholesome and properly labeled.”³ FDA has a duty to ensure that product labeling is not false or misleading in any particular.⁴

In a series of studies of 399 consumers conducted by researchers at the University of Oklahoma (the Feltz Study), respondents reported caring about ingredients in their food—chiefly citing reasons of health and allergy concerns.⁵ According to FDA, “[f]ood allergies are a significant public health concern with allergic reactions varying in severity from gastrointestinal disturbances and skin irritations to anaphylaxis, anaphylactic shock and death. Consumers with allergies must avoid food with allergenic materials to prevent serious health consequences since there is no cure.”⁶ In short, allergen and other health concerns are a key motivator for consumer interest in greater transparency—often effectuated through labeling transparency.

Despite the importance of identifying allergens via food labeling, current labeling requirements do not require disclosure of animal-derived ingredients that can cause severe reactions, including ingredients as common as meat broth, lard, or gelatin. This is because the majority of animal-derived ingredients do not constitute “major food allergens” under the Food Allergen Labeling and Consumer Protection Act of 2004. While this Act requires that foods containing “major food allergens” disclose the name of each major food allergen on their label,⁷ there are currently only nine major food allergens under federal law: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybeans, and sesame.⁸ This means that although a milk disclosure may alert consumers about the presence of lactose or whey, other allergens from mammals—from lard and gelatin to lanolin and pepsin—are not covered by current allergy labeling, despite the fact that

² See *U.S. v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change*, 409 F.2d 734, 740 (2d Cir. 1969) (“A primary purpose of the Act is the protection of the ultimate consumer’s economic interests.”); *United States v. Kocmond*, 200 F.2d 370, 373 (7th Cir. 1952) (“The purpose is to inform and protect the ultimate consumer.”) (citing *U.S. v. Dotterweich*, 320 U.S. 277 (1943)); *Barnes v. U.S.*, 142 F.2d 648, 651 (9th Cir. 1944) (“The purpose of the Act is the protection of the consuming public.”).

³ FDA, A FOOD LABELING GUIDE (2013), <https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf>.

⁴ 21 U.S.C. § 343(a).

⁵ In one study: 87% of respondents cited “health” as a reason for wanting to know their foods’ ingredients. 26% selected “allergies,” 7% selected religious reasons, and 3.1% selected “vegan” or “vegetarian.” In another study with the same value questions: 87.9% of respondents cited “health,” 32.7% cited allergies, 10% selected a religious reason, and 13.1% selected vegan or vegetarian. Ex. 2, Adam Feltz & Silke Feltz, Report on “Contains Animal-Derived Ingredients” Studies 1 and 2 (2024) (hereinafter “Feltz Report”).

⁶ FDA, FOOD ALLERGENS/GLUTEN-FREE GUIDANCE DOCUMENTS & REGULATORY INFORMATION, <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-allergensgluten-free-guidance-documents-regulatory-information>.

⁷ 21 U.S.C. § 343(w).

⁸ See *Food Allergies*, FDA, <https://www.fda.gov/food/food-labeling-nutrition/food-allergies> [<https://perma.cc/QZF4-6DPX>].

allergies to these ingredients are growing in prevalence, even small amounts of these ingredients can trigger severe allergic reactions, and these ingredients have a high allergenic potency.⁹

While understanding when a product contains animal-derived ingredients is important to consumers for general health reasons, it is *imperative* for those with certain food allergies. An alarming and growing risk, for example, has been the rise of alpha-gal syndrome, which has become more common in recent years and is spread to humans by the Lone Star tick.¹⁰ An allergy to alpha-gal can trigger severe allergic reactions to red meat, dairy products, and other foods that come from mammals.¹¹ That is because alpha-gal syndrome is an allergy to galactose- α -1,3-galactose, a molecule found in mammals such as cows, pigs, and sheep.¹²

Alpha-gal syndrome is a serious and sometimes life-threatening allergic condition. It has been found to have caused lethal anaphylaxis,¹³ as well as less severe reactions including shortness of breath, difficulty breathing, drop in blood pressure, swelling of the lips, throat, tongue, or eyelids, dizziness or faintness, and severe stomach pain.¹⁴ Reactions can be brought on by consuming animal-derived ingredients in food, including lanolin, lard, or gelatin; as well as by using cosmetics and medication that contain animal-derived ingredients. While the method of exposure does not determine the severity of the allergic reaction, and reactions may result from even trace amounts of alpha-gal, exposure to the allergen in food may result in a delayed reaction of greater than two hours after ingestion.¹⁵

Alpha-gal reactions are not uncommon, and they can be severe. While Yvonne Whitley broke out in hives after using a lotion that contained animal-derived ingredients,¹⁶ Ken McCullick's

⁹ See Ex. 3, THOMAS GALLIGAN ET AL., CTR. SCI. PUB. INTEREST, HIDDEN INGREDIENTS: WHAT ARE 'FLAVORS' AND 'SPICES,' AND ARE THEY SAFE? (2024) ("By not requiring labeling for other known food allergens while simultaneously allowing the use of the vague ingredient terms 'spices' and 'natural flavors,' the FDA allows the food industry to hide known allergens from consumers who need that information to protect themselves.") [hereinafter "CSPI Report"].

¹⁰ *Alpha-gal Syndrome*, CTR. FOR DISEASE CONTROL, <https://www.cdc.gov/ticks/alpha-gal/index.html> [<https://perma.cc/S3MR-ABYZ>].

¹¹ See *Alpha-gal syndrome*, MAYO CLINIC, <https://www.mayoclinic.org/diseasesconditions/alpha-gal-syndrome/symptoms-causes/syc-20428608> [<https://perma.cc/SB9E-4V42>].

¹² *Id.*

¹³ See Ex. 4, Shuheng Wen et al., *Fatal anaphylaxis due to alpha-gal syndrome after initial cetuximab administration: The first forensic case report*, 51 L. MED. 101878 (2021), <https://pubmed.ncbi.nlm.nih.gov/33892262/> (identifying a patient with alpha-gal syndrome who died from anaphylaxis after being given cetuximab, a drug made from goat's mammary glands); Chris Horne, *Suffolk woman with potentially deadly alpha-gal syndrome wants to raise awareness*, WAVY (May 4, 2023), <https://www.wavy.com/news/local-news/suffolk/suffolk-woman-with-potentially-deadly-alpha-gal-syndrome-wants-to-raise-awareness/> [<https://perma.cc/9WCE-UVDD>] (quoting allergist Dr. Eric Karlin as saying "there have been deaths reported in alpha-gal patients").

¹⁴ YALE MEDICINE, ALPHA-GAL SYNDROME, <https://www.yalemedicine.org/conditions/alpha-gal-syndrome-ags>.

¹⁵ Ex. 5, Chirag Patel et al., "Doc, Will I Ever Eat Steak Again?": *Diagnosis and Management of Alpha-gal Syndrome*, 32(6) CURRENT OP. PEDIATRICS 816 (Dec. 2021), <https://perma.cc/TEX3-MKV2>.

¹⁶ Horne, *supra* note 13.

heart stopped when he was given heparin, a blood thinner made from pig intestines.¹⁷ Half of all patients with alpha-gal syndrome have been found to exhibit “serious allergic reactions” after consuming products that contains mammalian-derived ingredients.¹⁸ Conservative estimates indicate that 450,000 Americans have likely contracted alpha-gal syndrome since 2010¹⁹—almost half the number of Americans who suffer from a sesame allergy (which FDA recently added to the list of major allergens). And this dangerous allergy is on the rise. Suspected cases of alpha-gal syndrome in the U.S. jumped 41% between 2017 and 2021, and the number of cases in the U.S. is predicted to increase during the coming years.²⁰ If FDA chooses not to require a disclosure identifying foods that contain animal-derived ingredients, FDA will put the health—and lives—of Americans at significant risk.

In addition to food safety regulations, the FDCA also prohibits false and misleading labeling—as failure to provide certain information could easily constitute consumer fraud.²¹ For this reason, FDA’s misbranding provisions include both affirmative statements and omissions.²² Section 321(n) defines “misbranded” food labels as:

labeling or advertising [which] fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.²³

Likewise, the FTC finds food advertising deceptive “if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material.”²⁴ While the FDCA does not specifically define the term

¹⁷ Brenda Goodman, *Mysterious meat allergy passed by ticks may affect hundreds of thousands in US, CDC estimates*, CNN (July 29, 2023), <https://www.cnn.com/2023/07/27/health/meat-allergy-alpha-gal-cdc/index.html> [<https://perma.cc/R8YH-7JCC>].

¹⁸ Hilary Tetenbaum, *Animal-derived ingredients in medicines can cause danger to human health, says VeganMed*, USA TODAY (Aug. 21, 2023), [<https://perma.cc/XQD5-ZKE7>].

¹⁹ ALPHA-GAL ALLIANCE, ALPHA-GAL INFORMATION, <https://alphagalinformation.org/>. YALE MEDICINE, ALPHA-GAL SYNDROME, <https://www.yalemedicine.org/conditions/alpha-gal-syndrome-ags> (noting that many cases go undiagnosed).

²⁰ Ex. 6, Julie M. Thompson et al., *Geographic Distribution of Suspected Alpha-gal Syndrome Cases — United States, January 2017–December 2022*, 72(30) CDC MORBIDITY & MORTALITY WKLY. REP. 815 (July 28, 2023).

²¹ 21 U.S.C. § 343(a).

²² *Id.* § 321(n).

²³ *Id.*

²⁴ FTC, ENFORCEMENT POLICY STATEMENT ON U.S. ORIGIN CLAIMS (Dec. 1, 1997), <https://www.ftc.gov/legal-library/browse/enforcement-policy-statement-us-origin-claims#e7> [<https://perma.cc/CA8X-64Z9>] (citing Letter from John C. Miller III, Chairman, Fed. Trade Comm’n, to John D. Dingell, Chairman, House Comm. on Energy & Com., on FTC Deception Policy Statement (Oct. 14, 1983),

“material” within the context of § 201(n), FDA has interpreted “‘materiality’ to mean information about the attributes of the food itself.”²⁵ Certainly whether a product contains trace ingredients that can trigger a life-threatening allergic reaction is material to consumers.²⁶

a. The suggested regulation is necessary not only to ensure consumer health and safety, but also access to important information.

i. Current labeling requirements fail to convey whether food products contain animal-derived ingredients.

Under current food labeling requirements, consumers cannot always discern whether a product contains animal ingredients. This is true at the store when consumers analyze product packaging,²⁷ as well as later on at home when consumers open and consume the food product in question. For example, animal-derived ingredients may be present in the form of an ingredient that can be sourced from either an animal or a plant—like Vitamin D²⁸—yet its source is not disclosed on the packaging. In a known real-world instance, a consumer contacted Planters asking about the gelatin in their roasted nut products. The company’s customer service was not able to tell the consumer whether the gelatin was pig- or cow-derived.²⁹ There is often no way for consumers to discern whether the ingredient is animal-derived, and if so from which animal, based on the information provided on the packaging or from analyzing the food contained therein. The table below provides just a few examples of such ingredients:

Ingredient	Sources	Uses
L-cysteine	Duck feathers, pig hair, hooves. Can also be made from plants or synthetically.	Dough softener in bagels, cookies, breads, pies, Lunchables, etc. Listed as “l-cysteine” without specifying source.

https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf [<https://perma.cc/8ZWL-M8PF>].

²⁵ FDA, FDA’S RESPONSE TO PUBLIC COMMENTS ON DRAFT GUIDANCE FOR INDUSTRY #187, Released 9/18/2008, <https://perma.cc/B6BV-C83U> (Section 201(n) provides that labeling is misleading if “it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual.”).

²⁶ For further discussion of materiality, *see infra* Section B.II.

²⁷ “It may be frustrating for consumers who are seeking to avoid animal products to learn that it is easier to spot animal-derived flavors on the label of a meat or poultry product than on the label of plant-based products regulated by the FDA.” Ex. 3, CSPI Report. Poultry can cause allergic reactions (“allergies to poultry meat are a distinct disorder with cross-reactivity among chicken, turkey, and other poultry. People with allergies to hen’s eggs may cross-react to other types of eggs (like duck and quail eggs) and poultry, especially chicken. While most people who are sensitive to eggs can eat chicken, one protein is present in both eggs and poultry that can cause allergies to both foods.”). FSIS WEBSITE, FOOD ALLERGIES: THE “BIG 9,” <https://perma.cc/X52W-QB38>.

²⁸ NAT’L INST. HEALTH, VITAMIN D FACT SHEET FOR HEALTH PROFESSIONALS, <https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/#h4>.

²⁹ Communications identifying consumer complaint, on file with ALDF.

Mono- and diglycerides	Often from animal fats but could be sourced from plant oils.	Emulsifier in margarine, nut butter, frosting, etc. Simply listed as “monoglycerides” or “diglycerides.”
Natural Vanilla Flavoring	Castoreum (beaver’s anal glands), or vanilla beans.	Used for vanilla flavoring.
Pepsin	Enzyme commonly sourced from pig stomachs. Less common but could be sourced from yeast.	Alternative to rennet in cheesemaking, simply listed as “enzymes.” Also used in foods like chewing gum, soy protein, instant cereal, nondairy snacks, and beverages.
Omega-3	Often from fish oil, sometimes from algae or seed oil.	Commonly used to fortify dairy milk, plant-based milk, orange juice, yogurt, pasta, granola bars, and other packaged foods.
Rennet	Enzyme commonly sources from cows, but also often microbially sourced.	Mostly used in dairy cheeses. Commonly appears as simply “enzymes” on ingredients list.
Vitamin A	Often from lanolin (sheep’s wool grease) but can be formulated from plant-based beta-carotene.	Commonly used to fortify all manner of foods, such as breakfast cereal, margarine, milk, juice, oil, and flour.
Vitamin D3	Often from lanolin (sheep’s wool grease) but can also be made naturally using lichen or algae or can be synthesized.	Commonly used to fortify animal-based and plant-based milks, orange juice, cereals, and other food products.

The asymmetry of information between food manufacturers and consumers makes most foods credence goods,³⁰ meaning that consumers cannot readily judge, even after visually inspecting and eating, the qualities of the product (here referring to the ingredients).³¹ In other words, consumers cannot determine whether products contain animal-derived ingredients even if they (1) are on notice that animal ingredients might be lurking in the ingredients list, (2) read the ingredients list, (3) scour the internet for each individual ingredient, and (4) contact the company. Thus, consumers know their preferences with respect to credence goods like food, but absent proper

³⁰ See Phillip Nelson, *Information and Consumer Behavior*, 78 J. POL. ECON. 311 (1970); Ex. 7, Dinah Cohen-Vernik et al., *Misrepresentation of Credence Goods and Channel Design* (Working Paper 2015).

³¹ More specifically, most foods have what Andersen & Philipsen refer to as “hidden credence characteristics,” because characteristics such as the animal source for individual ingredients are of the type that generally “cannot be detected by inspecting the finished good.” Ex. 8, ESSEN SLOTH ANDERSEN, AALBORG UNIV., & KRISTIAN PHILIPSEN, S. DEN. BUS. SCH., *THE EVOLUTION OF CREDENCE GOODS IN CUSTOMER MARKETS: EXCHANGING ‘PIGS IN POKES’* (1998).

labeling they cannot evaluate whether a product contains the characteristics they need or not.³² This creates market inefficiencies³³ and leads to consumers purchasing products they would not have purchased, had they been given accurate information—and ingesting products that conflict with their religious or other ethical code, or that risk triggering their allergies.³⁴ This makes proper labeling critical in credence goods markets.³⁵

ii. Current food products labeling requirements obfuscate animal-derived ingredients.

Despite the importance of ingredient information labeling to consumers, current food products labeling requirements fall short of a standard of transparency—and instead *create* consumer confusion. As FDA has acknowledged, consumers often form their understanding of a food’s ingredients based on the type of food.³⁶ Taking the example of the roasted nuts, or other seemingly straightforward foods, it is not unreasonable that consumers may assume a product is free of animal-derived ingredients. See below for some examples of products that consumers likely assume do not contain animal-derived ingredients that contain gelatin, whey, and lard, respectively.



Contains gelatin³⁷



Contains whey (milk)³⁸



Contains lard³⁹

³² See Ex. 9, FELIX GOTTSCHALK, ETH ZÜRICH, WHAT CHARACTERIZES CREDENCE GOODS? A CRITICAL LOOK AT THE LITERATURE (2018).

³³ See Uwe Dulleck et al., *The Economics of Credence Goods: An Experiment on the Role of Liability, Verifiability, Reputation, and Competition*, AM. ECON. REV. (2011).

³⁴ See *supra* note 13; *infra* II.

³⁵ Ex. 10, Nadia Cuffaro & Pascali Liu, *Technical regulations and standards for food exports: trust and the credence goods problem*, COMMODITY MKT. REV. (2008).

³⁶ See 21 C.F.R. § 102.5 (acknowledging that the labeling or the appearance of the food may create an impression that certain ingredients or components exist in a food product).

³⁷ Planters® Salted Dry Roasted Peanuts, <https://www.planters.com/product/planters-dry-roasted-peanuts-16-oz-jar/>.

³⁸ Gourmet Garden Garlic Stir-In Paste, <https://www.gourmetgarden.com/en-us/products/paste/garlic>.

³⁹ Grandma Utz Kettle-Style Potato Chips, <https://perma.cc/9MB5-45ET>.

What’s more, consumers may feel even more confident that they understand whether a product contains animal-derived ingredients if they read the ingredients list. The Feltz Study confirms consumers make these reasonable suppositions. As a part of the Feltz Study, participants were randomly shown eight product labels (PDPs) and eight ingredients lists. Half of the products contained animal-derived ingredients, and half did not. Participants were more likely than not to misidentify when a product contained animal-derived ingredients for both PDPs and ingredients lists. This means that a coin flip would be more accurate at identifying animal-derived ingredients than consumers—even after they evaluate the PDP or the ingredients list. The same was not true for fully plant-based products, where respondents were better than a guess at identifying the lack of animal-derived ingredients—especially when reading ingredients lists. This study demonstrates the inadequacy of the current labeling regime and the existing consumer confusion resulting from such inadequate labeling.

In the same study, participants were also shown a list of individually listed ingredients (*e.g.*, agar, whey) and asked to identify the animal-derived ingredients. Participants only correctly identified animal-derived ingredients 28% of the time (in contrast, they correctly identified plant-based ingredients 71% of the time). Looking at the data, the researchers summarized that the “results have one clear take-away . . . people were significantly worse than chance at accurately identifying the animal-derived products.” In other words, ***providing a list of ingredients “would not help people identify products with animal-derived ingredients”*** (emphasis added).

Current PDP labels confuse consumers as to the source of the products. As the Feltz Study shows, the current ingredients list does not cure that confusion. Rather, consumers are just as bad at understanding whether individual or lists of ingredients are derived from animals. The complex names and often opaque sourcing of ingredients (*e.g.*, monoglycerides and diglycerides can be sourced from either animal fats or from plant oils) means that the information currently available to consumers does not provide sufficient information for an average—or even highly sophisticated—American consumer to determine whether a product contains animal-derived ingredients.

II. Consumers value transparency in food labeling and have a significant interest in the disclosure of animal ingredients.

Americans strongly value transparency in food ingredients and labeling. 88.5% of respondents in the Feltz Study said they value knowing what ingredients are in their food.⁴⁰ Approximately half of all respondents to the Feltz Study also reported they would be upset if they found out that a food unexpectedly contained animal-derived ingredients.⁴¹ Studies confirming the strength of support among consumers for greater food product transparency have been repeatedly replicated.⁴²

Consumers’ interest in greater disclosure and transparency is significant and can be rooted not only in significant health concerns, as explained above, but also in religious beliefs, moral or

⁴⁰ Ex. 2, Feltz Report.

⁴¹ *Id.* (47% and 50.7%, respectively).

⁴² See, *e.g.*, Donna Berry, *Research Reveals the Power of Transparency*, FOOD BUS. NEWS (Nov. 22, 2023), [<https://perma.cc/Q5HD-WQQ8>] (a 2023 report by the Center for Food Integrity found that transparency was important to 76% of grocery shoppers); Press Release, Nielsen IQ, Consumer demand for food

ethical codes, or other health concerns. Several religions practiced by millions of Americans restrict or forbid the consumption of certain animals. For example, Hindus, of which there are approximately 2.5 million in the U.S.,⁴³ generally avoid eating beef, and many are vegetarian. Buddhists, of which there 4.2 million in the U.S.,⁴⁴ are commonly vegetarian or pescetarian. Seventh-day Adventists, of which there are approximately 1 million in the U.S.,⁴⁵ adhere to a strict lacto-ovo vegetarian diet. Muslims who eat a Halal diet, of which there are approximately 2.9 million in the U.S.,⁴⁶ and Jews who keep Kosher, of which there are approximately 1.3 million in the U.S.,⁴⁷ do not consume pork, and restrict the consumption of other animals. And there may be other religious restrictions regarding the consumption of animals as well. In short, as many as 12 million Americans may be impacted by religious diets that restrict the consumption of animal-derived foods. Beyond religion, a growing number of Americans choose to avoid consuming certain or all animal-

transparency remains strong as omnichannel rises (Jan. 25, 2022), [<https://perma.cc/Y2QF-U5N8>] (report finding that 64% of shoppers “say they would switch from a brand they usually buy to another brand that provides more in-depth product information?”); Krista Garver, *Global Consumers Trust Food Brands, But Seek Greater Transparency, DNV-GL Finds*, FOOD INDUS. EXEC. (July 15, 2020), <https://foodindustryexecutive.com/2020/07/global-consumers-trust-food-brands-but-seek-greater-transparency-dnv-gl-finds/> [<https://perma.cc/3JLF-LZUX>] (describing a survey finding that a majority of respondents want more transparency on product contents and allergens).

⁴³ HARVARD DIVINITY SCHOOL, RELIGION AND PUBLIC LIFE, HINDUISM CASE STUDY, <https://perma.cc/Y7ZD-B4XB>.

⁴⁴ WORLD POPULATION REVIEW, BUDDHIST COUNTRIES 2024, https://worldpopulationreview.com/country-rankings/buddhist-countries#google_vignette. See also Ex. 11, Jim McCaffree, *Dietary Restrictions of Other Religions*, 102 BUS. DIETETICS 912 (2002).

⁴⁵ Seventh-day Adventist Church, <https://www.adventist.org/world-church/north-american/>.

⁴⁶ PEW RESEARCH CENTER, DEMOGRAPHIC PORTRAIT OF MUSLIM AMERICANS, <https://www.pewresearch.org/religion/2017/07/26/demographic-portrait-of-muslim-americans/>; INST. SOCIAL POLICY AND UNDERSTANDING, AMERICAN MUSLIM POLL 2022, <https://ispu.org/halal-preferences/>.

⁴⁷ PEW RESEARCH CENTER, JEWISH AMERICANS IN 2020, (May 11, 2021), <https://www.pewresearch.org/religion/2021/05/11/jewish-americans-in-2020/>; PEW RESEARCH CENTER, JEWISH AMERICANS IN 2020, JEWISH PRACTICES AND CUSTOMS (May 11, 2021), <https://www.pewresearch.org/religion/2021/05/11/jewish-practices-and-customs/>.

derived products for reasons of personal ethics or other closely held beliefs.⁴⁸ Around 16.6 million Americans are either vegetarian or vegan.⁴⁹

For the religious, moral, food safety, and allergen concern reasons stated above, consumers have a significant interest in the disclosure of animal-derived ingredients.⁵⁰ This means that whether a food product contains animal-derived ingredients is a material fact for consumers. “The FDA [] consider[s] consumer opinion relevant when determining whether a label is required to disclose a material fact,”⁵¹ as is the case here. The difference between products that contain animals and those that do not is a material difference in type. For example, to someone with alpha-gal syndrome, it matters a great deal whether a product contains animal-derived ingredients that could trigger an allergic reaction.⁵² Similarly, to someone who cannot consume foods that come from cows or pigs for religious reasons, there is a very real difference between a food product that uses cow-derived rennet versus microbial-derived rennet,⁵³ or pig-derived pepsin versus yeast-derived pepsin.⁵⁴ The physical ingredients being used are different, and that matters to consumers.⁵⁵

⁴⁸ See Kelly Beaton, *The Continued Rise of the Flexitarian Diet*, FOOD INST. (June 19, 2023), [\[https://perma.cc/RZ2S-XC2W\]](https://perma.cc/RZ2S-XC2W); Daniel de Visé, *Vegetarianism is on the rise — especially the part-time kind*, HILL (Nov. 23, 2022), <https://thehill.com/changing-america/sustainability/3747206-vegetarianism-is-on-the-rise-especially-the-part-time-kind/> [\[https://perma.cc/C9ME-W4NK\]](https://perma.cc/C9ME-W4NK); F. Bailey Norwood & Courtney Bir, *1 in 10 Americans say they don't eat meat — a growing share of the population*, ALL. FOR SCI. (Mar. 10, 2022), <https://allianceforscience.org/blog/2022/03/1-in-10-americans-say-they-dont-eat-meat-a-growing-share-of-the-population/> [\[https://perma.cc/TBX3-CA5Z\]](https://perma.cc/TBX3-CA5Z).

⁴⁹ Jeffrey M. Jones, *In the U.S., 4% Identify as Vegetarian, 1% as Vegan*, Gallup (Aug. 24, 2023), <https://news.gallup.com/poll/510038/identify-vegetarian-vegan.aspx>. This number may coincide with the number of Americans who are vegetarian or vegan due to religious reasons.

⁵⁰ See *supra* II.

⁵¹ *Stanber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).

⁵² In the two Feltz studies, more than a quarter of respondents (26% and 32.7%, respectively) cited allergies as a reason for caring about knowing ingredients, and more than 87% selected health, generally, as a reason. Ex. 2, Feltz Report.

⁵³ For example, Boar’s Head states on its website that its Fontina Cheese is a “vegetarian product” and that its products can be trusted because Boar’s Head “make many of their cheese[s] without animal rennet.” *Fontina Cheese*, Boar’s Head, <https://boarshhead.com/products/detail/972-pre-cut-fontina-cheese#:~:text=Beverage%20Pairing&text=As%20a%20vegetarian%2C%20I%20trust,my%20fave%20snack%20worry%20free!> [\[https://perma.cc/FMM7-8UKG\]](https://perma.cc/FMM7-8UKG). However, nothing on the product packaging discloses to consumers that Boar’s Head Fontina Cheese is vegetarian friendly. Like almost all other cheeses, the ingredients list on the product simply includes “cheese cultures” and “enzymes” as ingredients, with no additional information.

⁵⁴ See Barbara Smith & Samantha Oller, *Clara Foods unveils first animal-free pepsin for commercial use*, FOOD DIVE (Mar. 11, 2021), <https://www.fooddive.com/news/clara-foods-unveils-first-animal-free-pepsin-for-commercial-use/596563/> [\[https://perma.cc/HUW4-JDSA\]](https://perma.cc/HUW4-JDSA).

⁵⁵ In the Feltz studies, between 7% and 10% of respondents listed some religious motivation (“Kosher,” “Halal,” or “Other Religious Reasons”) as the reason for caring about knowing ingredients. Ex. 2, Feltz Report.

As “there is a difference, and consumers would likely want to know about the difference, then labeling is appropriate.”⁵⁶ Thus, the inclusion of a “contains animal-derived ingredients” disclaimer “could be material to the consumer’s exercise of choice in deciding whether to buy the product.”⁵⁷ To prevent misbranding under the FDCA, FDA should require food labels to disclose whether they contain animal-derived ingredients.

a. Mandatory animal-derived ingredient disclosure will reduce consumer confusion.

An animal-derived ingredient disclaimer is highly effective at reducing consumer confusion. The Feltz Study revealed that including the disclaimer, “contains animal-derived ingredients,” on food products drastically increases consumers’ ability to distinguish whether a product contains animal-derived ingredients (in the Study, researchers presented consumers with a series of real products, some with a disclaimer added, and some without). These results held true regardless of whether the participants were comparing PDPs or ingredients lists.

To illustrate the exact findings, only 11% of respondents correctly identified that Rao’s Homemade Basil Pesto contained animal-derived ingredients when looking at the current PDP as it appears in store. Similarly, 20% identified Progresso’s Southwest-Style Black Bean Soup as containing animal-derived ingredients and only 6% identified Kind’s Dark Chocolate Nuts & Sea Salt as containing animal-derived ingredients. Respondents who were instead randomly shown those same PDPs with an additional “contains animal-derived ingredients” disclaimer correctly identified Rao’s, Progresso’s, and Kind bars as containing such ingredients **85%, 93%, and 83%** of the time, respectively.

Shockingly, even larger effects were found when respondents were randomly given ingredients lists with or without a “contains animal-derived ingredients” disclaimer along with the other allergens. Correct identification of such ingredients rose from 5.6% to 96.7% for WinCo Bagels, from 3.3% to 96.3% for General Mills’ Apple Cinnamon Cheerios, and from 30.8% to 93.5% for Planters Dry Roasted Peanuts. Aggregating across all products in the study, researchers found that for PDPs, a disclaimer improved participants’ ability to identify if a product contained animal-derived ingredients from 14% to 86%. For ingredients lists, a disclaimer similarly improved participants’ identification rate from 21% to 95%.

These dramatic leaps in accuracy confirm that current labeling laws leave the vast majority of consumers unable to accurately detect animal-derived ingredients even after inspecting the PDP and ingredients list. Most importantly, the empirical evidence available confirms that adding a disclaimer is highly effective at bridging the existing asymmetrical information gap.

III. The proposed rulemaking is in alignment with FDA’s stated policy goals and prior agency action.

FDA has stated that improving consumer education, particularly around transparency in ingredient and nutrition information, is an important policy goal for the agency. It has listed

⁵⁶ *Stauber*, 895 F. Supp. at 1193.

⁵⁷ *Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 95 (1st Cir. 2016).

“consumer education” as a key element of the agency’s nutrition initiative.⁵⁸ When FDA made changes to the Nutrition Facts Panel (NFP) in 2022, it justified the change in part because it would “make[] it easier for consumers to make better informed food choices.”⁵⁹ The requested rulemaking will further FDA’s stated policy goal by improving transparency and consumer understanding of nutritional details.⁶⁰ All this will make it easier for consumers to engage in informed decision making.

Further, FDA has recently taken the position that consumers can still be confused even when the NFP and ingredient list contain all the relevant information. In draft guidance for industry issued in early 2023, FDA asserted that consumers may be confused about plant-based milks despite the fact that the ingredients list and the NFP make the ingredients and comparative nutrition information clear.⁶¹ There, FDA took the position that even a detailed ingredients list (*i.e.*, one that makes clear a drink is made from almonds or oats and not cows’ milk) is not always enough to quell possible consumer confusion—all in spite of that fact that abundant evidence showed there is no consumer confusion over plant-based milk labeling.⁶² If that is FDA’s position, then the present labeling changes suggested in this petition are certainly warranted.

The requested rulemaking here is a response to a situation in which the ingredients list does not even contain all the relevant information. Consumers are thus unable to discern whether a product contains animal-derived ingredients or not, even after looking at the ingredients list.⁶³ As just one example, General Mills has stated that it sources Vitamin D3 from sheep’s lanolin⁶⁴—yet this information (and any reference to animal-derived ingredients) is missing entirely from the product packaging.⁶⁵ In a survey of consumers who were given the ingredients list for General Mills’ Apple Cinnamon Cheerios, only 3.3% correctly identified it as containing animal-derived ingredients without a disclaimer.⁶⁶ Once a disclaimer was added, 96.3% of respondents identified the product as

⁵⁸ FDA’s Nutrition Initiatives, FDA (Apr. 7, 2023), <https://www.fda.gov/food/food-labeling-nutrition/fdasnutrition-initiatives> [<https://perma.cc/4QJJ-7YPZ>].

⁵⁹ Changes to the Nutrition Facts Label, FDA (Mar. 7, 2022), <https://www.fda.gov/food/food-labeling-nutrition/changes-nutrition-facts-label> [<https://perma.cc/L7RF-7W3X>].

⁶⁰ See Ex. 2, Feltz Report (finding that “contains animal-derived ingredients” label disclosure greatly increased consumers ability to accurately identify whether a product contained animal-derived ingredients or not).

⁶¹ See, e.g., Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry, 88 Fed. Reg. 11449 (Feb. 23, 2023).

⁶² See ALDF Comment to FDA Re: Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements (Apr. 24, 2023), <https://www.regulations.gov/comment/FDA-2023-D-0451-0567>.

⁶³ Ex. 2, Feltz Report (After reviewing the ingredient list, most consumers were not able to correctly identify whether a product contained animal-derived ingredients. For example, in the Feltz’s second study, 30.8% of consumers correctly identified Planters Dry Roasted Peanuts as containing animal-derived ingredients, while that number was even lower for WinCo Bagels (5.6%), and General Mills Apple Cinnamon Cheerios (3.3%); see *supra* I.

⁶⁴ See *Do your cereals (General Mills and/or Cascadian Farm) contain any animal sourced ingredients?*, GEN. MILLS, <https://ask.generalmills.com/s/article/Do-your-cereals-General-Mills-and-or-Cascadian-Farm-contain-any-animal-sourced-ingredients> [<https://perma.cc/F5XD-WRW7>] (last accessed June 20, 2024).

⁶⁵ See, e.g., Ex. 12, General Mills Apple Cinnamon Cheerios label.

⁶⁶ Ex. 2, Feltz Report.

containing animal-derived ingredients.⁶⁷ Contrast this with FDA’s position on plant-based milk, in which all relevant nutrient information (*e.g.*, calcium, iron levels) that FDA is concerned about are already part of the NFP on the product package. Unlike with animal-derived ingredients, in the case of plant-based milk, there is ample evidence that consumers are *not* confused.⁶⁸ It logically follows that the agency should require disclosure statements for circumstances like hidden animal by-product ingredients where consumers are more likely to be confused or misled⁶⁹ and where current labeling requirements do not provide consumers with all the information needed.⁷⁰

In the past, FDA has issued rules “not based on any concern about the safety” of a product, but rather in response to the large number of comments “attest[ing] to the significance placed on such information by consumers.”⁷¹ In its irradiation rule, FDA made clear that the new labeling requirement was based on “whether the omission of label information may mislead a consumer.”⁷² In that case, FDA determined that consumers likely would be misled by whole food products that lacked the irradiation disclaimer.⁷³ In this petition, the requested rulemaking is based on both the significance put on disclosure by consumers⁷⁴ and by concerns about food safety and allergens.⁷⁵ As such, the requested rulemaking is in line with past FDA action and will further FDA’s stated policy goal in improving consumer education and ingredient transparency.

IV. FDA has authority to promulgate a rule requiring the disclosure of animal-derived ingredients.

FDA has statutory authority under the FDCA to promulgate the petitioned rule requiring front-of-package disclaimers of animal-derived ingredients. Section 343(q)(2)(A) permits the

⁶⁷ *Id.* The same study also showed participants the PDP for a different General Mills cereal, and the results held. Without a disclaimer, only 4% of respondents correctly identified the cereal as containing animal-derived ingredients. That number rose to 82% once a disclaimer was added to the PDP. *Id.*

⁶⁸ See Ex. 13, Silke Feltz & Adam Feltz, *Consumer Accuracy at Identifying Plant-based and Animal-based Milk Items*, 4(1) FOOD ETHICS 19 (2019) (finding no confusion between animal-based and plant-based milk products both labeled with the term “milk” and that participants consistently performed better when measuring differences between plant and animal-based milk products than when measuring the differences among animal-based milk products.); Ex. 14, Jared Gleckel, *Are Consumers Really Confused by Plant-Based Food Labels? An Empirical Study*, U. LOUISVILLE J. ANIMAL & ENVTL. L. (forthcoming) (finding that more participants—92% compared to 71%—were able to correctly identify “cultured vegan butter” as not containing dairy from cows); Ex. 15, GFI website, citing KERI SZEJDA, GOOD FOOD INST., CONSUMER PERCEPTIONS OF INGREDIENT SOURCES (2018) (finding that 96% of consumers understood soybeans to be the primary ingredient used to make soy milk—even higher than the accuracy rate for cow-based milks).

⁶⁹ See Ex. 2, Feltz Report.

⁷⁰ See *supra* II.

⁷¹ Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13376 (Apr. 18, 1986) (codified at 21 C.F.R. pt. 179).

⁷² *Id.* at 13388–90.

⁷³ See *id.*

⁷⁴ See Ex. 2, Feltz Report (finding that 88.5% of respondents value knowing what ingredients are in their food more than not); see also *supra* II.

⁷⁵ See *supra* II.

Secretary to, by regulation, require the disclosure of “information relating to [an] additional nutrient” be made on the label.⁷⁶ FDA further possesses the discretionary authority to “promulgate regulations for the efficient enforcement of [the FDCA].”⁷⁷

Furthermore, FDA and USDA have used such authority to issue comparable rules in the past, requiring label disclosures for the sole purpose of consumer education and interest. In 1986, for example, FDA issued a rule requiring food packaging disclosure statements for products that has been treated with radiation.⁷⁸ More recently, in 2018, USDA issued a final rule requiring that bioengineered foods be identified and disclosed as such on packaging labels.⁷⁹ The petitioned rule is in keeping with these prior uses of agency statutory authority.

V. Mandatory front-of-package ingredient disclosures are constitutional under the First Amendment.

The First Amendment of the U.S. Constitution protects freedom of speech, including commercial speech. However, under *Central Hudson*, the government may regulate commercial speech. Disclosure requirements imposed on commercial speech, such as ones suggested by the undersigned organizations, are subject to the lowest level of First Amendment scrutiny.⁸⁰ Here, the suggested mandatory front-of-package ingredient disclosure is strictly factual and uncontroversial. The Supreme Court has held that “factual and uncontroversial” information differs from opinion, and appellate courts have further ruled that “factual and uncontroversial” means not subjective—*i.e.*, factually accurate and nonideological.

C. Environmental Impact

Pursuant to 21 C.F.R. 10.30(3), petitioners submit that the action requested is subject to a categorical exclusion under 21 C.F.R. 25.30(h) and 25.30(k), and therefore does not require the preparation of an environmental assessment.⁸¹ Further, petitioners believe that the actions requested in this petition would have no environmental impact. The requested rulemaking would merely modify existing product labels and would not change the “levels of use or change in the intended uses” of impacted products.⁸²

⁷⁶ 21 U.S.C. § 343(q)(2)(A).

⁷⁷ *Id.* § 343(a)(1).

⁷⁸ *See* Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. at 13376.

⁷⁹ National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65814 (Dec. 21, 2018).

⁸⁰ When the government imposes a disclosure requirement in a commercial context, courts apply the test set forth by the Supreme Court in *Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626 (1985).

⁸¹ 21 C.F.R. § 25.30(h) creates a categorical exclusion for the issuance of procedural or administrative regulations, “including procedures for submission of applications for product development, testing and investigational use, and approval.” 21 C.F.R. § 25.30(k) likewise creates a categorical exclusion for the “[e]stablishment . . . of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.”

⁸² *See* 21 C.F.R. § 25.30(k).

D. Economic Impact

Although the Commissioner has not yet requested a statement of the economic impact of the requested action, petitioners offer a brief analysis because, although this petition will result in some temporary and minor cost increases to industry, the benefits to public health and economic efficiency will outweigh the costs.

The primary cost to industry associated with this rule would be the short-term cost of physically changing food packaging labels. The petitioned rule is not anticipated to cause any changes in food production, processing, segregation, or label making. Food manufacturers likely already have the necessary information about their ingredient sourcing,⁸³ the petitioned rule would merely require producers to share that information with consumers on the product itself. Further, any physical label change costs are likely to be negligible, as food producers regularly change product labels for marketing or other compliance reasons, and the petitioned rule would constitute a minor change. In a report prepared for the FDA, researchers noted that if a label change for regulatory compliance coincided with a regularly scheduled label change, costs would “not differ substantially.”⁸⁴ In other words, the cost for a minor graphic redesign like the addition of a disclaimer are no more than any other routine label change that companies regularly engage in.

The petitioned rule will likely have little to no effect on prices for consumers. An economic assessment of California’s Proposition 37, which mandates the disclosure of genetically engineered foods, found there would be “little to no change in consumer food prices as a result of [] relabeling expenses” as well as “negligible” administrative costs.⁸⁵ The reason the assessment’s author predicted no change for consumers was because relabeling expenses are a one-time “trivial expense for food sellers” and not worth the cost of repricing.⁸⁶ At most, the assessment predicted a possible one-time cost of \$1.27 for consumers.⁸⁷

The petitioned rule, along with rigorous enforcement of the rule, will benefit consumers and public health, as well as boost economic efficiencies by addressing the asymmetry of information facilitated by current labeling regulations. The status quo creates market inefficiencies. These inefficiencies can lead to market failures, including free-riding, moral hazard, and adverse selection.⁸⁸ Moral hazard, the risk that a party to a transaction may change their behavior to the detriment of others because they are protected or are unlikely to face consequences, may lead to “opportunistic

⁸³ See, e.g., *Do your cereals (General Mills and/or Cascadian Farm) contain any animal sourced ingredients?*, *supra* note 53.

⁸⁴ Ex. 16, Mary K. Muth et al., FDA Labeling Cost Model (2003).

⁸⁵ Ex. 17, JOANNA M. SHEPHERD-BAILEY, EMORY UNIV. SCH. OF L., ECONOMIC ASSESSMENT: PROPOSED CALIFORNIA RIGHT TO KNOW GENETICALLY MODIFIED FOOD ACT (PROP 37) LIKELY TO CAUSE NO CHANGE IN FOOD PRICES, MINOR LITIGATION COSTS, AND NEGLIGIBLE ADMINISTRATIVE COSTS.

⁸⁶ *Id.*

⁸⁷ *Id.*; see also Ex. 18, ANDREW DYKE & ROBERT WHELAN, ECONORTHWEST, GE FOODS LABELING COST STUDY FUNDINGS (2014) (finding that the annual grocery cost increase for consumers of a proposed mandatory GE labeling would be \$2.30, or less than a penny a day).

⁸⁸ Ex. 19, Peggy Schrobback et al., *Food Credence Attributes: A Conceptual Framework of Supply Chain Stakeholders, Their Motives, and Mechanisms to Address Information Asymmetry*, 12 FOODS 538 (2023).

behavior such as fraud or the provision of misleading information.”⁸⁹ Food labeling, like the petitioned rule, “can help combat consumer deception.”⁹⁰ Correcting for this informational asymmetry will reduce the risk of opportunistic behavior, and will grant consumers fuller knowledge with which to make purchasing decisions; meaning consumers can “satisfy[] their actual product preferences” thus more efficiently allocating resources.⁹¹ As a report prepared for USDA put it, transparent food labeling “may enhance economic efficiency by helping consumers to target expenditures toward products they most want.”⁹²

Asymmetric information can further expose consumers to health or other risks, as purchasers are unlikely to know if the food product conforms to their allergy, religious, or other dietary needs. The petitioned rule will make these inadvertent purchases less common,⁹³ improving consumer utility by providing for purchases more in-line with religious or moral belief systems, and will have the very real effect of decreasing the number of medical emergencies such as anaphylaxis caused by unknowingly consuming animal-derived ingredients. Thus, a mandatory disclaimer will have significant positive effects on the consumer, as well as secondary benefits to worker productivity, public health costs, and more.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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⁸⁹ *Id.* at 539.

⁹⁰ Josh Dhyani, *Science-Based Food Labels: Improving Regulations & Preventing Consumer Deception Through Limited Information Disclosure Requirements*, 26 ALB. L.J. SCI. & TECH. 1, 20 (2016).

Consumer deception occurs when (1) sellers have more knowledge of their product than consumers, (2) sellers disclose some information to consumers, (3) based on the disclosed information, consumers form expectations and beliefs (4) based on the formed expectations and beliefs, consumers make product choices, and (5) some of the consumers' beliefs and expectations are false.

Id.

⁹¹ *Id.*

⁹² Ex. 20, ELISE GOLAN ET AL., ECON. RSCH. SERV., USDA, ECONOMICS OF FOOD LABELING (2000).

⁹³ *See* Ex. 2, Feltz Report.



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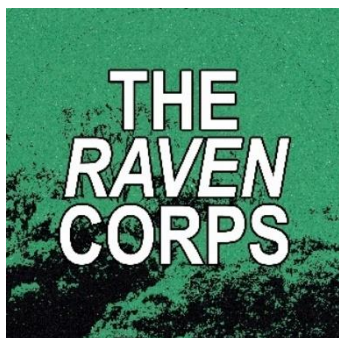
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*Petitioners sign in their individual capacity, and do not represent the position of the university, all members of the unit to which they belong, or the campus as a whole.

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