MARLER CLARK
THE FOOD SAFETY LAW FIRM

MARLER CLARK INC., PS | 180 Olympic Dr S.E., Bainbridge Island, WA 98110
TEL 1.206.346.1888 | FAX 1.206.346.1898 | marler@marlerclark.com | www.marlerclark.com

CITIZEN PETITION

Submitted under 21 CFR 10.30

Date: _____, 2026

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Submitted electronically at www.regulations.gov
Docket No. FDA-2013-S-0610

Re: Citizen Petition to Require a Consumer Warning Statement on the Labels of Packaged Raw and Lightly Cooked Sprouts

The undersigned submits this petition under sections 201(n), 403(a)(1), 403(f) and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n), 343(a)(1), 343(f) and 371(a)) and 21 CFR 10.30, and requests that the Commissioner of Food and Drugs issue a regulation requiring a warning statement on the labels of packaged raw and lightly cooked sprouts.

Twenty-eight years ago, this agency told children, the elderly and people with weakened immune systems not to eat raw sprouts, and later added pregnant women to that advice.[1] It has never withdrawn that advice. It has repeated it in 1999, in 2002, in guidance, and on the outbreak pages it has published and updated this month for the two sprout outbreaks that are open as this petition is filed. In all that time the advice has been delivered by press release, talk paper and web page. It has never once been delivered on the package. The petitioner asks the agency to put its own long-standing advice where the purchasing decision is made.

A. ACTION REQUESTED

The petitioner requests that the Commissioner take the following actions.

[1] FDA Press Release P99-13, *Consumers Advised of Risks Associated with Raw Sprouts* (July 9, 1999) (noting that "a previous advisory on this subject was issued August 31, 1998"), archived at https://webarchive.library.unt.edu/eot2008/20080916091946mp_/http:/www.cfsan.fda.gov/~lrd/hhssprts.html; FDA Talk Paper T02-37, *Consumers Advised of Risks Associated with Eating Raw and Lightly Cooked Sprouts* (Oct. 2, 2002), archived at https://webarchive.library.unt.edu/eot2008/20090511175647mp_/http:/www.cfsan.fda.gov/~lrd/tpsprout.html. See section V.

1. Require a prescribed warning statement. Amend 21 CFR 101.17 by adding a new paragraph (the designation to be assigned by the agency, referred to here as paragraph (i), the next letter available in a section that now runs through paragraph (h)) requiring that the label of any packaged sprouts that have not been processed by a validated method to prevent, reduce or eliminate pathogenic microorganisms bear the following statement, in the words prescribed:

> **WARNING:** Sprouts may contain harmful bacteria, such as *Salmonella*, *E. coli* and *Listeria*, that can cause serious illness, kidney failure or death. Sprouts are eaten raw and cannot be pasteurized, and the bacteria may be inside the seed, where washing cannot reach them. Children, the elderly, pregnant women, and persons with weakened immune systems should not eat raw or lightly cooked sprouts.

2. Define the covered product. For purposes of the new paragraph, "sprouts" should carry the meaning FDA already uses in 21 CFR 112.3, and the requirement should reach all sprouts covered by subpart M of part 112, including alfalfa, clover, radish, broccoli, mung bean and other bean sprouts, whether sold alone or as an identifiable ingredient of a packaged salad, sandwich, wrap or similar ready-to-eat food. Subpart M excludes sprouts grown in soil or a substrate and harvested above the soil line without their roots. 21 CFR 112.141. The petitioner asks that the warning requirement not carry that exclusion, for the reasons given in section II.

3. Prescribe the words rather than the elements. In the juice rulemaking FDA weighed two approaches to a warning: an "elements approach," under which the regulation would list the elements a statement must contain and leave each firm to write its own words, and a "prescriptive approach," under which the regulation states the exact text. Its focus group research showed that allowing variation in the words could produce a misleading message, and it concluded that a prescriptive statement is more effective, gives industry a clear standard, establishes a level playing field, and makes enforcement more straightforward. 63 FR 20486, 20490 (April 24, 1998). The petitioner asks the agency to take the same approach here, and uses "prescribed" in this petition in that sense.

4. Prescribe placement, prominence and type size. Require, as 21 CFR 101.17(g)(4) through (g)(6) require for juice, that the statement appear prominently and conspicuously on the information panel or the principal display panel; that the word "WARNING" be capitalized and appear in bold type; and that the statement be set off in a box by hairlines, as § 101.17 requires for juice at (g)(6), for iron-containing supplements at (e)(5) and for shell eggs at (h)(3). The petitioner further asks that the word "WARNING" immediately precede the statement, as FDA proposed for juice, 63 FR at 20491, and as paragraphs (d) and (e) of § 101.17 do in practice. On type size, the general minimum of 21 CFR 101.2(c) — one-sixteenth of an inch, about 4.5 points — is smaller than a statement of this kind should be. The petitioner asks that the statement appear in type no smaller than 8 point, the size FDA requires for the nutrient information in the

Nutrition Facts panel under 21 CFR 101.9(d)(1)(iii), and in no event smaller than § 101.2(c) requires.

5. Reach small packages and the unpackaged point of sale. For packages with less than 12 square inches of available label space, permit the statement to appear on a sign or placard at the point of sale in place of the label, in type not less than one-fourth inch in height, the size FDA set for juice placards under 21 CFR 101.100(a)(2)(ii). Require the same statement on a sign, placard or menu wherever raw or lightly cooked sprouts are offered to consumers in unpackaged form, including delicatessen counters, sandwich counters, salad bars and juice bars, and on the product listing wherever sprouts are offered for sale online. The juice rule expressly declined to reach unpackaged product, 63 FR at 20487, and the sprout record shows why that exclusion should not be repeated: a large share of documented sprout illnesses trace to sandwiches and restaurant meals rather than to retail packages.

6. Reach seed sold at retail for home sprouting. Require the same statement on the label of seed sold at retail for sprouting for human consumption. FDA has said that it considers seed for sprouting to be food, though not covered produce under part 112.[2] The alfalfa seed lot implicated in the 2026 outbreak was sold at retail, in small bags that carried no lot code, to home sprouters in forty-four states, and sprouts grown at home from contaminated seed carry the same organisms as sprouts grown commercially. See section VIII.

7. Exempt product that has been made safe. Exempt any sprouts cooked through before service, and any sprouts subjected to a process validated to achieve a reduction in the pertinent microorganism at least equal to the criterion the agency establishes. This mirrors the 5-log exemption in 21 CFR 101.17(g)(7) and gives the industry a path to the shelf without a warning rather than a verdict.

8. Set prompt effective and compliance dates. Make any final rule effective 60 days after publication, permit compliance by sign or placard in the interim as FDA proposed for juice at § 101.17(g)(3)(i) and (ii), 63 FR at 20491–92, and require the statement on the label itself by the next uniform compliance date for food labeling. For signs and placards the petitioner asks the agency to adopt the type size it set for juice, not less than one-fourth inch in height, 21 CFR 101.100(a)(2)(ii). Pending a final rule, the petitioner asks the agency to do what it did for juice on the day it published the proposal: urge sellers to begin using the proposed statement at once, by label or placard, and state that labels printed in conformity with the proposal may be used until inventories are exhausted. 63 FR at 20492.

9. Act expeditiously. The petitioner requests a response within the 180 days required by 21 CFR 10.30(e)(2) and asks that it be a decision on the merits rather than a tentative response. The petitioner also asks that the agency consider the same shortened comment period it used in the juice rulemaking, which it justified under Executive Order 12889 and

[2] FDA, *FDA Issues Final Guidance for Seeds Used for Sprouting*, Constituent Update (May 13, 2022) ("Although seed used for sprouting is not covered by the PSR, the FDA does consider seed used for sprouting to be food."), https://www.fda.gov/food/hfp-constituent-updates/fda-issues-final-guidance-seeds-used-sprouting.

21 CFR 10.40(b) on the grounds that the hazard was urgent and consumers needed the information as quickly as possible. 63 FR at 20492.

B. STATEMENT OF GROUNDS

Sections I through VIII set out the factual grounds for the petition: the hazard, the outbreak record, the federal advice, the Food Code, and the gap in the Produce Safety Rule. Sections IX through XIII set out the legal grounds and the precedents. Section XIV identifies the information unfavorable to the petition, as 21 CFR 10.30(b) requires.

I. The petitioner

William D. Marler is the managing partner of Marler Clark, Inc., PS, a law firm whose practice is devoted to the representation of people injured by contaminated food. He has represented victims of foodborne illness since 1993 and has represented plaintiffs in sprout-related outbreaks, including the 2009 Caudill Seed Company alfalfa sprout outbreak, the Jimmy John's clover sprout outbreaks, the 2013–14 sprouted chia seed powder outbreak, the 2014 Wonton Foods mung bean sprout outbreak, and the 2016 Sprouts Extraordinaire alfalfa sprout outbreak. He first asked FDA to require a warning statement on raw sprouts in March 2003, during a Salmonella outbreak traced to sprouts in Oregon, Washington and California, and repeated that request publicly in June 2014 following an *E. coli* O121 outbreak traced to clover sprouts from Evergreen Fresh Sprouts, LLC, and again in December 2014 during the Wonton Foods outbreak that ultimately sickened 115 people in 12 states.[3] The petitioner notes, without asking the agency to draw anything from it beyond the fact itself, that Evergreen Fresh Sprouts is the grower in one of the two outbreaks open as this petition is filed.

II. Sprouts present a distinct hazard that the agency has already characterized

The hazard is not disputed and has not changed in three decades. Seeds intended for sprouting are grown as an agricultural commodity, often in open fields, and may carry enteric pathogens when they arrive at the sprouting facility. The conditions required to germinate a seed — warmth, moisture, nutrients and time — are the conditions under which those pathogens multiply. A small number of organisms on a seed can become an infectious dose in the finished product. Because the organisms may be internalized within the seed, washing the sprouts does not remove them, and the finished product is eaten

[3] Marler Clark, *Food Safety Attorney Calls on FDA to Require Sprout Labeling* (Mar. 18, 2003), https://marlerclark.com/news_events/food-safety-attorney-calls-on-fda-to-require-sprout-labeling; *Time for a Warning Label on Sprouts*, Food Poison Journal (June 2014), https://www.foodpoisonjournal.com/foodborne-illness-outbreaks/william-marler-time-for-a-warning-label-on-sprouts/; *As Another Salmonella "Sproutbreak" Grows, Marler Calls for Sprout Warning Label*, Food Poison Journal (Dec. 2014), https://www.foodpoisonjournal.com/food-policy-regulation/as-another-salmonella-sproutbreak-grows-marler-calls-for-sprout-warning-label/. CDC, *Multistate Outbreak of Salmonella Enteritidis Infections Linked to Bean Sprouts* (Final Update, Jan. 23, 2015) (115 people in 12 states), https://archive.cdc.gov/www_cdc_gov/salmonella/enteritidis-11-14/index.html.

raw. FDA has stated this reasoning in its own words in guidance issued in 2019 and again in May 2022, and CDC published the same conclusion in a peer-reviewed article in 1999.[4]

FDA has also stated that contaminated seed is the likely source of most sprout-related outbreaks.[5] That single sentence is the reason a warning statement is warranted: the agency has identified the point in the chain that causes most of the harm and has separately explained that the point is outside the reach of the rule it wrote. See section VIII below.

The hazard does not stop at the soil line. Subpart M excludes sprouts grown in soil or a substrate and harvested above the soil line without their roots. 21 CFR 112.141. That line was drawn for a process rule. For the consumer the question is simpler: a sunflower, pea or broccoli shoot eaten raw is an immature plant eaten without a kill step, and in the 2026 broccoli sprout outbreak one patient reported eating a microgreen mix containing broccoli microgreens rather than sprouts; the agencies have not said who grew it, and the recall covers broccoli sprouts only.[6] The petitioner asks in section A.2 that the warning follow the product rather than the growing method, and asks the agency to take up the question on the record.

III. The outbreak record

FDA's own May 2022 guidance to the sprout seed industry states that between 1996 and 2020 there were 52 reported outbreaks of foodborne illness associated with contaminated sprouts in the United States, together causing more than 2,700 illnesses.[7] That figure counts one country, counts only reported outbreaks, and stops in 2020. An earlier version of the same guidance, issued in draft in 2019, counted 50 outbreaks and more than 2,600 illnesses through August 2018.[8] An earlier accounting, published by FDA in January 2017 and covering 1996 through July 2016, counted 46 outbreaks, 2,474 illnesses, 187 hospitalizations and three deaths.[9] Read together, the agency's own counts show a slower pace after the subpart M compliance dates — six outbreaks between mid-2016 and the

---

[4] Taormina, Beuchat & Slutsker, *Infections Associated with Eating Seed Sprouts: An International Concern*, Emerging Infectious Diseases, vol. 5, no. 5 (1999), https://wwwnc.cdc.gov/eid/article/5/5/99-0503_article.

[5] FDA, *FDA Issues Draft Guidance for Reducing Food Safety Hazards in the Production of Seed for Sprouting*, Constituent Update (June 24, 2019), https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-draft-guidance-reducing-food-safety-hazards-production-seed-sprouting.

[6] FDA, *Outbreak Investigation of Salmonella: Sprouts (September 2026)* (update of Sept. 24, 2026) (of 27 people interviewed, 22 reported broccoli sprouts and one reported a microgreen mix containing broccoli microgreens), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-sprouts-september-2026.

[7] FDA, *Guidance for Industry: Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting* (May 2022), Docket No. FDA-2018-D-4534, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-reducing-microbial-food-safety-hazards-production-seed-sprouting. The figures are also stated in the constituent update announcing the guidance, *FDA Issues Final Guidance for Seeds Used for Sprouting* (May 13, 2022), https://www.fda.gov/food/hfp-constituent-updates/fda-issues-final-guidance-seeds-used-sprouting.

[8] FDA Constituent Update (June 24, 2019), https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-draft-guidance-reducing-food-safety-hazards-production-seed-sprouting.

[9] FDA, *FDA Announces Draft Guidance to Help Sprout Operations Comply with Produce Safety Rule*, Constituent Update (Jan. 19, 2017), https://www.fda.gov/food/constituent-updates/fda-announces-draft-guidance-help-sprout-operations-comply-produce-safety-rule.

end of 2020, against roughly two a year in the two decades before — and the petitioner does not argue otherwise. The point is narrower: the rule has not ended sprout outbreaks. The record since FDA's count closed includes the 2022–23 *Salmonella* Typhimurium outbreak linked to SunSprout Enterprises alfalfa sprouts, which sickened 63 people in eight states and hospitalized ten,[10] and the two outbreaks open as this petition is filed, one of them at a grower that received a Produce Safety Rule warning letter in 2025.

The international record is worse. Contaminated fenugreek seed sprouted in Germany caused the 2011 outbreak of *E. coli* O104:H4 that produced the largest cluster of hemolytic uremic syndrome on record, with thousands ill and dozens dead across Europe. Fifteen years earlier, the largest *E. coli* O157:H7 outbreak ever recorded, in Japan in 1996, was linked to white radish sprouts: roughly 6,000 of nearly 10,000 cases. A second radish sprout outbreak followed in 1997, and seed was identified as the likely source of both.[11] Sprout outbreaks have been recorded on four continents.[12]

Repeat involvement by the same firms is a feature of this record. Evergreen Fresh Sprouts, LLC has been linked to outbreaks in 2011, in 2014 and again in 2026.[13] FDA issued warning letters to two sprout operations within a nine-day window in March 2025, one of which is the grower in the 2026 alfalfa outbreak; that letter noted that a deficiency observed in 2024 had also been observed in inspections of the same facility in 2023 and 2018.[14]

IV. Two outbreaks are open as this petition is filed

Product and brands	Grower	Cases	States	Hospitalized

[10] *CDC Declares Salmonella Outbreak Linked to Sprouts Over*, Food Safety News (Mar. 1, 2023) (SunSprout Enterprises alfalfa sprouts; 63 ill in eight states, ten hospitalized; recall Dec. 29, 2022), https://www.foodsafetynews.com/2023/03/cdc-declares-salmonella-outbreak-linked-to-sprouts-over/.
[11] Taormina, Beuchat & Slutsker, *Infections Associated with Eating Seed Sprouts: An International Concern*, Emerging Infectious Diseases, vol. 5, no. 5, at 626–34 (1999) (radish sprouts linked to approximately 6,000 of nearly 10,000 cases in Japan in 1996; a second radish sprout outbreak in 1997; seed the likely source of both), https://doi.org/10.3201/eid0505.990503; CDC Press Release, *Sprouts: Not a Healthy Food for Everyone* (Aug. 9, 1999); Phyllis Entis, *Tainted: From Farm Gate to Dinner Plate, Fifty Years of Food Safety Failures*, ch. 8 (both producers used seed bought in 1995 from the same United States distributor).
[12] German Federal Institute for Risk Assessment (BfR), reporting Robert Koch Institute figures: nearly 4,000 infected and 53 dead, and, measured by cases of hemolytic uremic syndrome, the largest outbreak of its kind described anywhere in the world. https://www.bfr.bund.de/en/ehec_outbreak_2011-186689.html. On the single lot of fenugreek seed from Egypt common to the German and French outbreaks, European Food Safety Authority (July 5, 2011), https://www.efsa.europa.eu/en/press/news/110705.
[13] On the 2014 clover sprout outbreak, https://www.foodpoisonjournal.com/foodborne-illness-outbreaks/william-marler-time-for-a-warning-label-on-sprouts/. On the 2026 broccoli sprout outbreak, FDA outbreak investigation (Sept. 2026), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-sprouts-september-2026.
[14] FDA warning letter to Everything Sprouts, LLC, MARCS-CMS 699480 (Mar. 28, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/everything-sprouts-llc-699480-03282025; FDA warning letter to Jack & The Green Sprouts, Inc., MARCS-CMS 697257 (Mar. 19, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jack-green-sprouts-inc-697257-03192025.

Alfalfa sprouts (Calco, Everything Sprouts)	Everything Sprouts, LLC	55	15	4
Broccoli sprouts	Evergreen Fresh Sprouts, LLC	32	6	3

Table 2. Sprout outbreaks open in September 2026, from the CDC outbreak pages updated September 1 and September 24, 2026. Washington and Minnesota appear on both lists, so the combined footprint is 87 people in 19 states, seven of them hospitalized.[15]

The alfalfa outbreak involves four organisms in one product — *Salmonella* Agona and three serogroups of Shiga toxin-producing *E. coli* — with two patients carrying organisms from two genera. Traceback identified a common alfalfa seed lot and at least one additional grower that received and used seed from that lot.[16] The broccoli sprout outbreak involves a different grower, a different state and a different serotype, and FDA has said the two are unrelated. On September 24 FDA reported that broccoli sprouts collected in Washington from a grocery store and from a sick person's home had both tested positive for the outbreak strain: the organism was on the retail shelf, in a package that said nothing.[17][18] Both firms have now recalled. The broccoli sprout recall could not have reached most of the people it was meant to protect: the recalled bags were delivered between August 24 and September 2, and twenty-five of the thirty-two illnesses had begun by August 23.[19] Neither package carried a warning before anyone became ill.

These two outbreaks are the occasion for this petition, not its basis. The basis is the twenty-eight-year record set out in the sections that follow. If both investigations closed tomorrow, every ground stated in this petition would still hold.

V. FDA has advised high-risk consumers to avoid raw sprouts continuously since 1998

On August 31, 1998, FDA advised children, the elderly and persons with weakened immune systems not to eat raw alfalfa sprouts. The agency reissued that advisory on July 9, 1999, in Press Release P99-13, with Commissioner Jane Henney stating that despite the measures the industry had tried, the best way for high-risk consumers to control the

[15] CDC investigation notices, https://www.cdc.gov/ecoli/outbreaks/alfalfa-sprouts-08-26/index.html and https://www.cdc.gov/salmonella/outbreaks/broccoli-sprouts-09-26/index.html.
[16] FDA outbreak investigation, sprouts (Aug. 2026), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-shiga-toxin-producing-e-coli-salmonella-sprouts-august-2026.
[17] FDA, *Outbreak Investigation of Salmonella: Sprouts (September 2026)* (update of Sept. 24, 2026) (broccoli sprouts collected from a Washington grocery store and from a sick person's home both matched the outbreak strain), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-sprouts-september-2026.
[18] FDA outbreak investigation, Salmonella, sprouts (Sept. 2026), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-sprouts-september-2026.
[19] *Evergreen Fresh Sprouts LLC Recalls Broccoli Sprouts Because of Possible Health Risk* (Sept. 10, 2026) (recalled bags delivered to three distributors between August 24 and September 2, 2026), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/evergreen-fresh-sprouts-llc-recalls-broccoli-sprouts-because-possible-health-risk; CDC, *When People Got Sick: Salmonella Outbreak, September 2026* (illness onset dates), https://www.cdc.gov/salmonella/outbreaks/broccoli-sprouts-09-26/timeline.html.

risk was not to eat raw sprouts.[20] On October 2, 2002, in Talk Paper T02-37, FDA extended the advisory to raw and lightly cooked mung bean sprouts, stated that adherence to the 1999 sprout guidance had not been universal and that outbreaks had continued, and added that hospitals, day care centers, nursing homes and senior centers should not serve sprouts.[21]

The advisory has never been withdrawn or softened. It appears, in substance, on the FDA and CDC pages published for each of the two outbreaks open as this petition is filed.[22] It is also current standing advice. FDA's July 2020 guide for older adults and people with cancer, diabetes, HIV/AIDS, organ transplants and autoimmune diseases lists raw sprouts of any kind among the higher-risk foods to avoid, lists cooked sprouts as the lower-risk choice, and tells readers eating out to ask that raw or lightly cooked sprouts be left off.[23] The 1998, 1999 and 2002 advisories named children, the elderly and people with weakened immune systems; the agency later added pregnant women, and its consumer guidance for pregnant women now tells them to avoid raw sprouts of any kind.[24]

VI. CDC has published the same advice since 1999

In 1999 CDC authors wrote in the agency's own peer-reviewed journal that treatments of seed and sprouts cannot remove all the bacteria present, that the germination conditions favor bacterial growth, and that persons at high risk should probably not eat raw sprouts at all.[25] CDC has repeated that advice on the sprout outbreak notices it has posted since, including the two open now.

Two federal agencies have therefore told the same population the same thing, without interruption, for more than a quarter century, through a channel that reaches a consumer only if she happens to read a press release on the day it is issued. A press release has the

---

[20] FDA first issued the advisory on August 31, 1998 and reissued it on July 9, 1999. The 1999 statement is archived at https://webarchive.library.unt.edu/eot2008/20080916091946mp_/http:/www.cfsan.fda.gov/~lrd/hhssprts.html.

[21] FDA Talk Paper T02-37 (Oct. 2, 2002), archived at https://webarchive.library.unt.edu/eot2008/20090511175647mp_/http:/www.cfsan.fda.gov/~lrd/tpsprout.html.

[22] FDA, https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-shiga-toxin-producing-e-coli-salmonella-sprouts-august-2026 and https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-sprouts-september-2026; CDC, https://www.cdc.gov/ecoli/outbreaks/alfalfa-sprouts-08-26/index.html and https://www.cdc.gov/salmonella/outbreaks/broccoli-sprouts-09-26/index.html.

[23] FDA, *Food Safety for Older Adults and People with Cancer, Diabetes, HIV/AIDS, Organ Transplants, and Autoimmune Diseases* (July 2020), at 3, 11 ("Raw sprouts (alfalfa, bean, or any other sprout)" listed as higher risk; "Cooked sprouts" as lower risk), https://www.fda.gov/media/83744/download.

[24] FDA, *Food Safety for Moms-to-Be*, "The Sprout Issue" (advising pregnant women to avoid raw sprouts of any kind), https://www.fda.gov/food/resourcesforyou/healtheducators/ucm082417.htm; FDA and USDA, *Food Safety for Pregnant Women* (booklet, first issued August 2012), available through FDA's Education Resource Library.

[25] CDC Press Release, *Sprouts: Not a Healthy Food for Everyone* (Aug. 9, 1999), https://www.cdc.gov/media/pressrel/r990809.htm, announcing Taormina, Beuchat & Slutsker, *Infections Associated with Eating Seed Sprouts: An International Concern*, Emerging Infectious Diseases, vol. 5, no. 5 (1999), https://wwwnc.cdc.gov/eid/article/5/5/99-0503_article.

shelf life of one news cycle. A package sits in a refrigerator until somebody eats what is inside it.

Date	Federal statement
August 31, 1998	FDA advises children, the elderly and persons with weakened immune systems not to eat raw alfalfa sprouts.
July 9, 1999	FDA reissues the advisory; Commissioner Jane Henney states that the best way to control the risk is not to eat raw sprouts.
August 9, 1999	CDC announces, in a press release titled "Sprouts: Not a Healthy Food for Everyone," findings published in *Emerging Infectious Diseases* that seed and sprout treatments cannot remove all bacteria present and that persons at high risk should probably not eat raw sprouts.
October 2, 2002	FDA Talk Paper T02-37 extends the advisory to raw and lightly cooked mung bean sprouts and states that hospitals, day care centers, nursing homes and senior centers should not serve sprouts.
2017–2019	Sprout-specific compliance dates take effect under 21 CFR part 112, subpart M.
July 2020	FDA's guide for older adults and people with weakened immune systems lists raw sprouts of any kind among the higher-risk foods to avoid, and cooked sprouts as the lower-risk choice.
May 2022	FDA guidance on seed for sprouting records 52 U.S. sprout outbreaks from 1996 through 2020 and more than 2,700 illnesses.
September 2026	CDC and FDA outbreak pages for both open sprout outbreaks repeat the same advice to the same populations.

Table 1. The federal position on raw sprouts, 1998 to 2026. Every entry is advice or guidance. None of these statements appear on a package.

VII. The finding that supports a warning has already been made, in the Food Code

Section 3-801.11(C)(3) of the FDA Food Code provides that raw seed sprouts may not be served or offered for sale in a ready-to-eat form in a food establishment that serves a highly susceptible population — hospitals, nursing homes, assisted living facilities, child and adult day care centers and senior centers. FDA publishes the Food Code, drawing on recommendations from the Conference for Food Protection, as a model for the state and local agencies that regulate restaurants and retail food stores, and the states adopt it as their own law. FDA added raw seed sprouts to that list in the 1999 edition, the year after

its first advisory.[26] The Food Code's Annex 3 gives the public health reason: raw seed sprouts have been a recognized source of foodborne illness since 1995, and FDA and CDC advised people at greater risk to avoid them until interventions improved the product's safety.[27] The interventions arrived with subpart M in 2017. The advice did not change. Every edition since 1999 has carried the provision; according to FDA's adoption reports every state but California has adopted an edition of the Food Code, and California's own Retail Food Code contains the same prohibition.[28] The same section, at paragraph (A)(2), bars those establishments from serving juice that bears the warning statement required by 21 CFR 101.17(g). The Food Code already uses an FDA warning label as the marker for what may not be served to the most vulnerable; for sprouts it names the product, because there is no label to point to.[29]

The determination embedded in that provision is the determination this petition asks the agency to act on. FDA has already concluded, in a model code the states enforce, that raw sprouts are too dangerous to place in front of a frail eighty-five-year-old woman. She is protected at dinner in the nursing home. She drives to the grocery store and buys the identical product, in a package that says nothing at all. The same gap exists for the pregnant woman, the toddler and the patient in the middle of chemotherapy. The Food Code stops at the front door of the institution. The hazard does not.

VIII. The Produce Safety Rule regulates the sprouter; it reaches the seed only at the sprouter's door

Sprouts are the only produce commodity with a dedicated subpart in the Produce Safety Rule. Subpart M of 21 CFR part 112, part of the Produce Safety Rule published at 80 FR 74353 on November 27, 2015, requires covered sprout operations to take measures against the introduction of pathogens into seed, to test spent sprout irrigation water or in-process sprouts for certain pathogens, to test the growing, harvesting, packing and holding environment for *Listeria* species, and to take corrective action. Compliance dates ran from January 26, 2017 for the largest operations through January 28, 2019 for very small ones.[30] The subpart exists because FDA found that the distinctive practices and conditions for growing sprouts present unique risks, and said so when it wrote the rule and again in the guidance that implements it.[31]

---

[26] 64 FR 8576 (Feb. 22, 1999) (notice of availability of the 1999 Food Code: "For establishments serving highly susceptible populations, enhanced food safety protections are added with respect to raw shell eggs, juices, and raw seed sprouts"), https://www.gpo.gov/fdsys/pkg/FR-1999-02-22/html/99-4315.htm.
[27] FDA Food Code 2022, Annex 3 (Public Health Reasons and Administrative Guidelines), discussion of § 3-801.11, https://www.fda.gov/media/164194/download.
[28] FDA, *Adoption of the FDA Food Code by State and Territorial Agencies Responsible for the Oversight of Restaurants and Retail Food Stores* (2024 annual report), https://www.fda.gov/food/fda-food-code/adoption-fda-food-code-state-and-territorial-agencies-responsible-oversight-restaurants-and-retail; Cal. Health & Safety Code § 114091(e)(3), https://california.public.law/codes/ca_health_and_safety_code_section_114091.
[29] FDA Food Code, § 3-801.11(C)(3), https://www.fda.gov/media/164194/download. FDA publishes the current state adoption status of the Food Code.
[30] FSMA Final Rule on Produce Safety, subpart M compliance dates, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety.
[31] 80 FR 74353 (Nov. 27, 2015); FDA, *Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption* ("Because the distinctive practices and

The subpart reaches the seed only when it arrives at the sprouter. Section 112.142 requires the sprout operation to take measures against the introduction of hazards into the seed it will use, to stop using and report any lot it has reason to believe is contaminated, and to treat the seed with a scientifically valid method to reduce pathogens immediately before sprouting, or to document that its supplier did so. What the subpart does not reach is the seed grower, conditioner or distributor. FDA has said so directly: it considers seed used for sprouting to be outside the definition of covered produce, and the growing, conditioning and distribution of that seed to be outside the scope of covered activities.[32] The agency addressed the gap with guidance in May 2022, and guidance, by its own terms, does not bind anyone. Treatment at the sprouter narrows the gap; it does not close it. FDA's own seed guidance states that seed treatments may reduce, but not eliminate, pathogens on seed for sprouting,[33] and the organisms that do the harm may be inside the seed, where a surface treatment does not reach. FDA nonetheless treats seed for sprouting as food, which is why the labeling authority discussed in section IX reaches it.[34]

The result is a regulatory structure in which the agency has identified contaminated seed as the likely source of most sprout outbreaks, has excluded seed production from the binding rule, and has addressed it with a document that creates no obligation. [35]The pattern is not new: in the 2012 *E. coli* O26 outbreak, FDA traced the clover sprouts served at six Jimmy John's restaurants to a single lot of seed that had been sprouted by multiple firms — one lot, several growers, one outbreak.[36] The 2026 alfalfa outbreak shows the gap operating in real time. On August 31, 2026, FDA reported that it had recommended that the common seed supplier recall the implicated lot and notify its downstream customers, and that the supplier had not responded, had not sent a recall notice, and had not instructed its customers to recall. On September 15 the agency reported that the supplier had agreed to recall the lot, which had been sold to sprout growers and wholesale distributors in sixteen states and Puerto Rico, shipped to Canada, Mexico, Tahiti and Venezuela, and "may have been sold at the retail level." On September 23 an Ohio seed retailer recalled 950 pounds of alfalfa sprouting seed from the same lot, sold in its store and online to customers in forty-four states between February and August; its quarter-,

conditions for growing sprouts present unique risks, we established sprout-specific requirements in Subpart M"), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-standards-growing-harvesting-packing-and-holding-sprouts-human-consumption.

[32] FDA Constituent Update (June 24, 2019), https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-draft-guidance-reducing-food-safety-hazards-production-seed-sprouting ("we consider the seeds used for sprouting to be outside the definition of 'covered produce' under the rule").

[33] FDA, *Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Guidance for Industry* (May 2022) ("Seed treatments may reduce, but not eliminate, pathogens on seed for sprouting"), https://www.fda.gov/media/127972/download; 21 CFR 112.142.

[34] FDA, *FDA Issues Final Guidance for Seeds Used for Sprouting*, Constituent Update (May 13, 2022), https://www.fda.gov/food/hfp-constituent-updates/fda-issues-final-guidance-seeds-used-sprouting.

[35] FDA outbreak investigation, sprouts (Aug. 2026), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-shiga-toxin-producing-e-coli-salmonella-sprouts-august-2026.

[36] FDA Warning Letter to Jimmy John's Franchise, LLC, MARCS-CMS 599962 (Feb. 21, 2020) (2012 outbreak: "FDA identified a single lot of seed grown and distributed by multiple sprouting firms"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jimmy-johns-franchise-llc-599962-02212020.

half- and one-pound bags carried no lot code, and one illness had been reported directly to the company. As of September 24, FDA's advisory still did not name the supplier.[37]

The juice warning was adopted precisely because a process rule would take years. For sprouts, the process rule exists and does not apply to the part of the chain that causes most of the harm. The case for informing the consumer is stronger now than it was for juice in 1998, not weaker.

IX. The legal grounds: FDA has the authority, and has used it for exactly this purpose

FDA's authority to require a warning statement on a food derives from sections 201(n), 403(a)(1) and 701(a) of the Act. Under section 403(a)(1), a food is misbranded if its labeling is false or misleading in any particular. Under section 201(n), in determining whether labeling is misleading the agency must consider the extent to which the labeling fails to reveal facts material with respect to consequences that may result from use of the product under customary conditions of use. Section 701(a) authorizes regulations for the efficient enforcement of the Act. Section 403(f) requires that mandatory label information appear with such conspicuousness as to render it likely to be read and understood by the ordinary individual.

The agency set out this exact chain of authority in the juice labeling proposal and cited two earlier exercises of it: the warning on protein products, 49 FR 13679 (April 6, 1984), and the warning on iron-containing dietary supplements, 62 FR 2218 (January 15, 1997). 63 FR at 20487.

The material-fact analysis transfers to sprouts without strain. A consumer selecting a clamshell of alfalfa sprouts is not told that the product may carry pathogens that can kill her, that the organisms may be inside the seeds where washing cannot reach them, that the product cannot be pasteurized, or that two federal agencies have advised people in her circumstances not to eat it. Those are facts material with respect to the consequences of consuming the product under customary conditions of use. Unless disclosed at the time the purchase decision is made, packaged raw sprouts are misbranded within the meaning of sections 201(n) and 403(a)(1).

The point has additional force for sprouts because of how they are marketed and perceived. FDA observed in the juice rulemaking that a warning is especially important where consumers do not historically regard a product as hazardous and where the product is promoted and consumed as part of a healthy diet. 63 FR at 20489. Sprouts are sold, and understood, as one of the healthiest things in the produce case.

A compelled disclosure of this kind is consistent with the First Amendment. A requirement that a seller disclose purely factual and uncontroversial information about

---

[37] FDA, *Outbreak Investigation of Shiga Toxin-producing E. coli & Salmonella: Sprouts (August 2026)* (updates of Aug. 31, Sept. 15 and Sept. 24, 2026), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-shiga-toxin-producing-e-coli-salmonella-sprouts-august-2026; *Berlin Seeds Recalls Alfalfa Sprouting Seed Because of Possible Health Risk* (Sept. 23, 2026), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/berlin-seeds-recalls-alfalfa-sprouting-seed-because-possible-health-risk.

its product, reasonably related to a substantial government interest, is reviewed under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985), and the D.C. Circuit, sitting en banc, has held that the standard is not limited to disclosures that correct deception. *American Meat Institute v. U.S. Department of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). The Supreme Court has since said that it does not question "the legality of health and safety warnings long considered permissible." *National Institute of Family and Life Advocates v. Becerra*, 585 U.S. 755, 768 (2018). The statement proposed here recites facts the agency has published continuously since 1998, names the groups the agency has itself identified, and gives the advice the agency has itself given. It is drafted to be short, factual and free of opinion or imagery, which is one reason the petitioner has not asked that the full list of documented consequences appear on the package. See section XII.

X. FDA has required comparable statements before, and so has FSIS

The action requested here is not novel. It is the next entry in a section of the labeling regulations the agency has been building since 1977, and it has a close counterpart at the Food Safety and Inspection Service.

Product	Agency and citation	Rule	Hazard disclosed
Protein products for weight reduction	FDA, 21 CFR 101.17(d)	49 FR 13679 (Apr. 6, 1984)	Serious injury or death from use without medical supervision
Iron-containing dietary supplements	FDA, 21 CFR 101.17(e)	62 FR 2218 (Jan. 15, 1997)	Accidental overdose is a leading cause of fatal poisoning in children under six
Raw and partially cooked meat and poultry	FSIS, 9 CFR 317.2(l), 381.125(b)	59 FR 14528 (Mar. 28, 1994)	Inspected product may still carry bacteria that cause illness
Juice not processed to a 5-log reduction	FDA, 21 CFR 101.17(g)	63 FR 37030 (July 8, 1998)	Harmful bacteria; greatest risk to children, the elderly and people with weak immune systems
Shell eggs not treated to destroy *Salmonella*	FDA, 21 CFR 101.17(h)	65 FR 76092 (Dec. 5, 2000)	Illness from bacteria; refrigerate and cook until yolks are firm
Major food allergens	FDA, FDCA 403(w)	FALCPA, Pub. L. 108-282 (2004)	Presence of an ingredient that can cause anaphylaxis

Mechanically tenderized beef	FSIS, 9 CFR 317.2(e)(3)	80 FR 28153 (May 18, 2015)	Surface pathogens carried into the interior of an intact cut

Table 3. Mandatory consumer safety statements already required on FDA- and FSIS-regulated foods. In every case the agency identified a hazard the shopper could not see and required the seller to disclose it. Raw sprouts, the subject of the longest-standing federal consumer advisory of any food on this list, carry no statement.

The agency's own warning section already carries four of these, and a fifth besides. Section 101.17 of title 21 is where FDA puts food labeling warning, notice, and safe handling statements. The section dates to 1977, and the agency has added consumer safety statements to it steadily since: protein products for weight reduction at paragraph (d) in 1984, iron-containing dietary supplements at paragraph (e) in 1997, psyllium husk at paragraph (f), untreated juice at paragraph (g) in 1998, and shell eggs at paragraph (h) in 2000. One of those statements has already been tested in court and survived. The unit-dose packaging provisions adopted alongside the iron warning were held beyond FDA's authority in Nutritional Health Alliance v. FDA, 318 F.3d 92 (2d Cir. 2003), and withdrawn at 68 FR 59714 (Oct. 17, 2003). The warning statement at § 101.17(e) was untouched and remains in force. Granting this petition adds paragraph (i) to a section built for exactly this purpose. It does not require the agency to adopt a new doctrine, a new authority, or a new labeling architecture.

Shell eggs are the closest analogue, and sprouts present the stronger case. On December 5, 2000, at 65 FR 76092, FDA required a prescribed safe handling statement on every carton of shell eggs not specifically processed to destroy *Salmonella* and made it effective nine months later. The parallels are close: a raw agricultural commodity; a pathogen that is invisible, odorless and tasteless; contamination that can be internal rather than on the surface; a consumer who has no way to tell a contaminated unit from a clean one; word-for-word prescribed text that may not be shortened or paraphrased; and an exemption for product treated to destroy the organism, which is what in-shell pasteurization provides.

Juice is the closer analogue in purpose, because its warning addresses the same vulnerable groups; shell eggs are the closer analogue in form. The remaining distinction cuts in the petitioner's favor. FDA required the egg statement even though the consumer holds a complete remedy in her own kitchen: an egg cooked until the yolk is firm is safe, and the required statement says so. A sprout eaten as sprouts are intended to be eaten has no such remedy. There is no cooking step, and there is no washing step that reaches an organism inside the seed. The commodity with no consumer kill step is the one commodity in this table carrying no statement at all.

FSIS has done the same thing under a different statute. On March 28, 1994, at 59 FR 14528, the Food Safety and Inspection Service made safe handling instructions mandatory on the labels of all raw and partially cooked meat and poultry products, fourteen months after the Jack in the Box *E. coli* O157:H7 outbreak; the petitioner represented the most seriously injured survivor of that outbreak. The required statement, codified at 9 CFR 317.2(l) and 381.125(b), tells the shopper that the product was prepared

from inspected and passed meat or poultry and that some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly — a federal agency conceding, on every package, that its inspection does not guarantee the absence of pathogens. The petitioner recognizes that FSIS acts under the Federal Meat Inspection Act and the Poultry Products Inspection Act rather than the Federal Food, Drug, and Cosmetic Act, and that a safe handling instruction is a different kind of statement from a warning addressed to vulnerable consumers. The point is a narrow one: the government already requires a prescribed, word-for-word microbial safety statement, in a set format and a minimum type size, on the products it inspects most closely, and requires none on a product it has advised high-risk consumers to avoid for twenty-eight years.

The mechanically tenderized beef rule supports the effective date requested in section A.8. On May 18, 2015, at 80 FR 28153, FSIS required that raw and partially cooked needle- or blade-tenderized beef carry the designation "mechanically tenderized" on the principal display panel, with validated cooking instructions, because tenderization can carry surface pathogens into the interior of a cut and the consumer cannot tell a tenderized steak from an intact one. FSIS made the rule effective in May 2016 rather than waiting for the January 1, 2018 uniform compliance date, citing the public health significance of the change.[38]

The consumer's position is the same here: the contamination may be internal, the package looks like every other package, and the information sits entirely with the seller.

XI. The juice rule is the template, and FDA built it in seventy-five days

After the unpasteurized juice outbreaks of the mid-1990s, including the 1996 apple juice *E. coli* O157:H7 outbreak that sickened at least 66 people and killed a child,[39] FDA proposed a warning statement on April 24, 1998, published a final rule on July 8, 1998 at 63 FR 37030, and made it effective September 8, 1998 for apple juice and cider, in time for that year's cider season, and November 5, 1998 for all other juices. The rule sits at 21 CFR 101.17(g).

FDA explained why it moved in that order. A HACCP program was the better long-term control, but rulemaking and implementation would take years, and during that period the risk would persist; unless warned, consumers at greatest risk could suffer serious illness and even death. Implementation of a labeling requirement, the agency wrote, can be completed more quickly than implementation of a mandatory HACCP program. 63 FR at 20487. The juice HACCP rule followed at 66 FR 6138 on January 19, 2001, two and a half years later. The label came first and carried the interval.

---

[38] USDA FSIS, *USDA Finalizes Rule to Require Labeling of Mechanically Tenderized Beef Products* (May 13, 2015), https://www.fsis.usda.gov/news-events/news-press-releases/usda-finalizes-rule-require-labeling-mechanically-tenderized-beef.

[39] 63 FR 20486, 20486 (Apr. 24, 1998), https://www.govinfo.gov/content/pkg/FR-1998-04-24/html/98-11026.htm.

Sprouts received the opposite sequence. They got the process rule, in 2017 through 2019. They have never received the label. Twenty-eight years after the advisory and nearly a decade after the subpart M compliance dates, two outbreaks are open at once.

XII. The proposed statement satisfies the agency's own criteria for an effective warning

In the juice rulemaking FDA identified three essential elements of an effective warning statement, drawn from its consumer research: a description of the hazard, appearing in the first sentence; a statement of why the labeled product presents that hazard; and an identification of the groups at greatest risk. 63 FR at 20489. The statement proposed in section A contains all three.

The statement departs from the juice text in four respects, each deliberate. First, the hazard sentence names the consequences — serious illness, kidney failure or death — rather than "serious illness" alone, because the sprout record includes hemolytic uremic syndrome in children and deaths, and because FDA's research found that a warning is credible when the hazard is described rather than merely asserted. 63 FR at 20489. Second, the juice warning opens by saying the product has not been pasteurized. That opening cannot be borrowed, because sprouts cannot be pasteurized: the heat that kills the bacteria also kills the seed. The proposed statement says so and adds the one fact that distinguishes sprouts from every other raw vegetable — that the organisms may be inside the seed, where washing cannot reach them. Third, the statement tells the at-risk consumer what to do. In 1998 FDA asked whether an explicit instruction to avoid the product should be required for juice and concluded that the instruction was implicit in the warning. 63 FR at 20489. For sprouts it should be explicit, because an explicit instruction not to eat raw sprouts is what FDA and CDC have been giving these groups since 1998. Fourth, the statement names pregnant women, whom the juice warning does not. FDA's consumer guidance for pregnant women tells them to avoid raw sprouts of any kind, and the sprout record includes *Listeria*, which threatens the pregnancy itself.

The petitioner acknowledges that FDA's focus group research found that consumers preferred a short, concise statement, 63 FR at 20490, and has drafted accordingly: the statement requested in section A runs about sixty words, with the hazard in the first sentence. The petitioner's longer text, which names the documented consequences of these infections — bloody diarrhea, hemolytic uremic syndrome, Guillain-Barré syndrome, reactive arthritis, irritable bowel syndrome, miscarriage and death — was published on September 11, 2026,[40] and is offered here as consumer-education material and as candidate text for point-of-sale placards rather than as label copy. Each consequence it names is documented in the sprout literature and in the medical records of people the petitioner has represented. The juice rule itself permitted signs and placards for a period, so the placard mechanism sits within the same rulemaking.

[40] William Marler, *Two Sprout Outbreaks Are Open Right Now and Seventy-Seven People Are Sick*, Marler Blog (Sept. 11, 2026), https://www.marlerblog.com/case-news/two-sprout-outbreaks-are-open-right-now-and-seventy-seven-people-are-sick-fda-has-told-high-risk-consumers-to-stay-away-from-raw-sprouts-since-1998-and-not-one-word-of-that-warning-appears-on-the-pa/.

XIII. Voluntary action by retailers is not a substitute, and the retailers have already made the finding

Several of the largest food retailers and restaurant chains in the country examined this evidence and concluded that they would not sell the product. Walmart removed raw sprouts from its United States stores and clubs in October 2010, citing the inherent microbial risks associated with sprouts. Jason's Deli dropped them across 230 restaurants in January 2012 and said it had lost confidence in sprouts. Erbert and Gerbert's removed alfalfa sprouts system-wide in February 2012 and announced it. Kroger, then 2,425 stores in 31 states, stopped selling them on October 22, 2012, and its food safety director explained that pathogens can be inside the seed where processing cannot reach them — the same reason CDC gave in 1999 and FDA gives now.[41]

Two conclusions follow. The first is that the hazard is neither speculative nor contested; sophisticated buyers with their own food safety staffs reached the agency's conclusion independently. The second is that a private decision protects only the customers of that firm, lasts only as long as the firm wants it to, and is never communicated to the shopper. Walmart's decision was a quiet one; the customer who stopped finding sprouts on the shelf was never told why. The petitioner does not ask FDA to take sprouts off the market. The retailer decisions are cited for the finding behind them, not for the remedy the retailers chose; a warning leaves the product on the shelf and the decision with the shopper.

Jimmy John's illustrates the durability problem. The chain announced in February 2012 that clover sprouts were gone permanently, told FDA three months later that it would continue serving sprouts from approved suppliers, and was linked to further outbreaks. On February 21, 2020, FDA issued the chain a warning letter describing a pattern of receiving and offering for sale adulterated produce across five outbreaks in seven years affecting consumers in no fewer than 17 states.[42] It took a warning letter, and eight more years, to accomplish what a labeling rule would have accomplished on the shelf in 1998 for every brand at once.

XIV. Information known to the petitioner that is unfavorable to this petition

As 21 CFR 10.30(b) requires, the petitioner identifies representative information unfavorable to the position taken here.

First, FDA has said that labeling may have limited effectiveness because a warning must be read and be understood, and it described the juice warning as a measure of public safety pending a process rule rather than a solution. The petitioner does not contend that

---

[41] Walmart (Oct. 2010), https://www.barfblog.com/2012/02/walmart-stopped-selling-raw-sprouts-over-a-year-ago-for-food-safety-reasons-why-havent-others/; Jason's Deli and the broader retail retreat (Jan. 2012), https://www.npr.org/sections/thesalt/2012/01/27/145922622/from-health-food-to-health-risk-sprouts-slip-off-the-menu; Erbert and Gerbert's (Feb. 2012), https://www.prnewswire.com/news-releases/erbert-and-gerberts-sandwich-shops-remove-alfalfa-sprouts-from-menu-139528153.html; Kroger (Oct. 22, 2012), https://www.foodsafetynews.com/2012/10/kroger-to-stop-selling-sprouts/.

[42] FDA warning letter to Jimmy John's Franchise, LLC, MARCS-CMS 599962 (Feb. 21, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jimmy-johns-franchise-llc-599962-02212020.

a label prevents contamination. A label transfers a decision to the person who bears the consequence, which is a smaller claim and a defensible one.

Second, the juice warning was expressly a bridge to HACCP, and sprouts already have a process rule. The agency could conclude on that basis that the bridge is unnecessary. The answer is in section VIII: the rule does not reach the seed grower, treatment at the sprouter cannot reach organisms inside the seed, and FDA has identified the seed as the likely source of most outbreaks. The petitioner acknowledges that FDA's own counts show fewer outbreaks a year after the compliance dates than before them, and does not claim the rule has failed. The claim is that it has not finished the job: outbreaks have continued after the compliance dates passed, and the consumer the agency has told to avoid the product is still not told at the point of sale.

Third, portions of the sprout industry have invested substantially in seed treatment, spent irrigation water testing and environmental monitoring, and some firms have long records without an outbreak. A prescribed warning does not distinguish between them and the firms with repeat histories. The petitioner accepts that consequence for the same reason the agency accepted it for juice: the consumer cannot tell the two apart at the case, and the exemption requested in section A.7 gives any firm that validates a treatment a route out of the requirement.

Fourth, a warning statement can be misread as permission — as an indication that a product carrying the words may lawfully be sold in whatever condition it is in. The petitioner asks that any preamble state expressly that the warning is not a defense to adulteration under section 402 and does not diminish any obligation under part 112.

Fifth, labeling changes impose costs, and the sprout industry includes a large number of small and very small businesses. The petitioner asks the agency to address this the way it did for juice, through a placard alternative during a transition period and a later compliance date for small businesses, rather than by weakening the statement.

Sixth, most fresh produce carries no safety warning, and a sprout-specific requirement singles out one commodity. It does. The agency has already singled out the same commodity twice, in subpart M of part 112 and in section 3-801.11(C)(3) of the Food Code, and on the same reasoning.

Seventh, not every sprout outbreak begins with seed. Some have been traced to insanitary conditions inside sprouting facilities, and the proposed statement's reference to bacteria inside the seed should therefore be read as one route among several, which is why the proposed language says the bacteria may be inside the seed rather than that they are.

Eighth, the precedents in section X show both that labels can calcify and that an agency can conclude a label is not enough. The FSIS safe handling instructions have not been redesigned since 1994. A coalition of consumer organizations that included STOP Foodborne Illness petitioned FSIS in May 2016 to modernize them, and FSIS denied the

petition in May 2022 while continuing consumer research on a revised label.[43] In the same month of 2016 the National Chicken Council asked FSIS to require a uniform "raw" label with validated cooking instructions on not-ready-to-eat breaded stuffed chicken products; in May 2024 FSIS instead declared *Salmonella* an adulterant in those products, finding that years of labeling changes and consumer outreach had not prevented outbreaks.[44] The petitioner raises these facts because they are true and because they bear on the remedy. A label rule should be written to be revisable, and a petition should be answered rather than left open. The stuffed chicken experience does not transfer to sprouts. Those labels failed because consumers cooked a raw product as if it were already cooked; the statement requested here does not depend on a cooking step at all. It tells identified groups not to eat the product, which is the advice the agency already gives, and it supplements a binding process rule rather than substituting for one.

Ninth, there is a literature on warning fatigue suggesting that proliferating label warnings lose force. The petitioner notes that the requested statement would be the sixth consumer safety statement added to 21 CFR 101.17 since 1984, in a section that has carried warning and notice statements since 1977. That is not a proliferation.

Tenth, compelled warnings have been struck down where a court found them not purely factual, or more burdensome than the government's interest required. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012) (graphic cigarette warnings). The statement requested here is text only, recites facts the agency has published for twenty-eight years, and is no longer than those facts require. The petitioner has drafted it with that decision in mind, and section IX explains why the disclosure standard, not the standard applied to the graphic warnings, governs it.

XV. Conclusion

Twenty-eight years of consistent federal advice. More than fifty American outbreaks by the agency's own count, and more than 2,700 illnesses. A finding already made in the Food Code that this product is too dangerous to serve to susceptible people. A regulatory rule that reaches the sprouter but not the seed the agency has identified as the likely source. Two outbreaks open at once, eighty-seven people sick, seven in the hospital. A template the agency wrote in seventy-five days in 1998 and has enforced ever since on a bottle of cider.

Everything needed to write this rule is already in the agency's files. The only piece missing is the sentence on the bag.

C. ENVIRONMENTAL IMPACT

[43] Safe Food Coalition, Petition 16-04 (May 31, 2016); FSIS, Final Response to Petition 16-04 (May 31, 2022), https://www.fsis.usda.gov/sites/default/files/media_file/2022-06/16-04-Final-Response-05312022.pdf.

[44] FSIS Petition 16-03, National Chicken Council (May 24, 2016), https://www.fsis.usda.gov/federal-register/petitions/establish-labeling-requirements-not-ready-eat-stuffed-chicken-products; *Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products*, final determination, 89 FR 35033 (May 1, 2024), https://www.federalregister.gov/documents/2024/05/01/2024-09393/salmonella-not-ready-to-eat-breaded-stuffed-chicken-products.

The petitioner claims a categorical exclusion under 21 CFR 25.30(k). The action requested is of a type that does not individually or cumulatively have a significant effect on the human environment, and neither an environmental assessment nor an environmental impact statement is required. FDA made the same determination under the same provision for the juice labeling proposal. 63 FR at 20491.

D. ECONOMIC IMPACT

Information on economic impact will be submitted upon request of the Commissioner following review of this petition, in accordance with 21 CFR 10.30(b).

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,

William D. Marler
Marler Clark, Inc., PS
180 Olympic Drive S.E.
Bainbridge Island, Washington 98110
Telephone: 1-800-884-9840
bmarler@marlerclark.com

Sources cited — Citizen Petition on a Warning Statement for Raw Sprouts

Marler Clark, Inc., PS · September 2026. The regulatory, enforcement and public health sources below are free government publications; the retailer and chain decisions are cited to contemporaneous news accounts and company statements; the cases in section IX are cited to the official reporters, and the book in section III by chapter, without links.

Regulations

21 CFR 10.30 — Citizen petition.
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-10/subpart-B/section-10.30

21 CFR 101.17 — Food labeling warning, notice, and safe handling statements.
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-A/section-101.17

21 CFR 101.9(d)(1)(iii) — Nutrition labeling; minimum type size.

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-A/section-101.9

9 CFR part 317 — FSIS labeling; safe handling instructions at 317.2(l), mechanically tenderized beef at 317.2(e)(3).
https://www.ecfr.gov/current/title-9/chapter-III/subchapter-A/part-317

9 CFR 381.125 — Special handling label requirements for poultry.
https://www.ecfr.gov/current/title-9/chapter-III/subchapter-A/part-381/subpart-N/section-381.125

California Health and Safety Code § 114091 — Retail Food Code, highly susceptible populations (raw seed sprouts at subdivision (e)(3)).
https://california.public.law/codes/ca_health_and_safety_code_section_114091

Federal Register

Juice labeling, proposed rule, 63 FR 20486 (April 24, 1998).
https://www.govinfo.gov/content/pkg/FR-1998-04-24/html/98-11026.htm

Juice labeling, final rule, 63 FR 37030 (July 8, 1998).
https://www.govinfo.gov/content/pkg/FR-1998-07-08/html/98-18287.htm

Iron-containing dietary supplements and drugs: label warning statements, 62 FR 2218 (January 15, 1997).
https://www.govinfo.gov/content/pkg/FR-1997-01-15/html/97-947.htm

Mandatory safe handling statements on raw meat and poultry, 59 FR 14528 (March 28, 1994).
https://www.govinfo.gov/content/pkg/FR-1994-03-28/html/94-7217.htm

Safe handling statements and labeling of shell eggs, 65 FR 76092 (December 5, 2000).
https://www.federalregister.gov/documents/2000/12/05/00-30761/food-labeling-safe-handling-statements-labeling-of-shell-eggs-refrigeration-of-shell-eggs-held-for

Juice HACCP, 66 FR 6138 (January 19, 2001).
https://www.federalregister.gov/documents/2001/01/19/01-1291/hazard-analysis-and-critical-control-point-haacp-procedures-for-the-safe-and-sanitary-processing-and

Mechanically tenderized beef, 80 FR 28153 (May 18, 2015).
https://www.federalregister.gov/documents/2015/05/18/2015-11916/descriptive-designation-for-needle--or-blade-tenderized-mechanically-tenderized-beef-products

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Safety Rule), final rule, 80 FR 74353 (November 27, 2015).
https://www.federalregister.gov/citation/80-FR-74353

Iron-Containing Supplements and Drugs; removal of the unit-dose packaging regulations following Nutritional Health Alliance v. FDA, 68 FR 59714 (October 17, 2003).
https://www.govinfo.gov/content/pkg/FR-2003-10-17/html/03-26188.htm

Protein products warning, 49 FR 13679 (April 6, 1984). Predates the free online Federal Register, which begins in 1994; cited by FDA at 63 FR 20487.
Availability of the 1999 Food Code, 64 FR 8576 (February 22, 1999).
https://www.gpo.gov/fdsys/pkg/FR-1999-02-22/html/99-4315.htm

Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products, final determination, 89 FR 35033 (May 1, 2024).
https://www.federalregister.gov/documents/2024/05/01/2024-09393/salmonella-not-ready-to-eat-breaded-stuffed-chicken-products

Cases

Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985).
American Meat Institute v. U.S. Department of Agriculture, 760 F.3d 18 (D.C. Cir. 2014) (en banc).
National Institute of Family and Life Advocates v. Becerra, 585 U.S. 755 (2018).
Nutritional Health Alliance v. FDA, 318 F.3d 92 (2d Cir. 2003).
R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012).

Books

Phyllis Entis, Tainted: From Farm Gate to Dinner Plate, Fifty Years of Food Safety Failures, chapter 8 (the 1996–97 Japanese radish sprout outbreaks).

FDA guidance, advisories and enforcement

FDA Food Code, section 3-801.11(C)(3).
https://www.fda.gov/media/164194/download

FDA, Adoption of the FDA Food Code by State and Territorial Agencies Responsible for the Oversight of Restaurants and Retail Food Stores, 2024 annual report.
https://www.fda.gov/food/fda-food-code/adoption-fda-food-code-state-and-territorial-agencies-responsible-oversight-restaurants-and-retail

FDA, Food Safety for Older Adults and People with Cancer, Diabetes, HIV/AIDS, Organ Transplants, and Autoimmune Diseases (July 2020).
https://www.fda.gov/media/83744/download

FDA advisory on raw sprouts, July 9, 1999 (archived).
https://webarchive.library.unt.edu/eot2008/20080916091946mp_/http:/www.cfsan.fda.gov/~lrd/hhssprts.html

FDA Talk Paper T02-37, October 2, 2002 (archived).
https://webarchive.library.unt.edu/eot2008/20090511175647mp_/http:/www.cfsan.fda.gov/~lrd/tpsprout.html

FDA constituent update on seed for sprouting, June 24, 2019.
https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-draft-guidance-reducing-food-safety-hazards-production-seed-sprouting

FDA constituent update announcing the final seed guidance, May 13, 2022 (52 outbreaks and more than 2,700 illnesses, 1996–2020; seed for sprouting is food).
https://www.fda.gov/food/hfp-constituent-updates/fda-issues-final-guidance-seeds-used-sprouting

FDA constituent update on the draft sprout operations guidance, January 19, 2017 (46 outbreaks, 2,474 illnesses, 187 hospitalizations and three deaths, 1996–July 2016).
https://www.fda.gov/food/constituent-updates/fda-announces-draft-guidance-help-sprout-operations-comply-produce-safety-rule

Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-standards-growing-harvesting-packing-and-holding-sprouts-human-consumption

Guidance for Industry: Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting (May 2022).
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-reducing-microbial-food-safety-hazards-production-seed-sprouting

Guidance for Industry: Exemptions from the Warning Label Requirement for Juice.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exemptions-warning-label-requirement-juice

FSMA Final Rule on Produce Safety, including subpart M compliance dates.
https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety

Evergreen Fresh Sprouts LLC recall of broccoli sprouts (September 10, 2026).
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/evergreen-fresh-sprouts-llc-recalls-broccoli-sprouts-because-possible-health-risk

Berlin Seeds recall of alfalfa sprouting seed (September 23, 2026).
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/berlin-seeds-recalls-alfalfa-sprouting-seed-because-possible-health-risk

FDA warning letter to Everything Sprouts, LLC, MARCS-CMS 699480 (March 28, 2025).
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/everything-sprouts-llc-699480-03282025

FDA warning letter to Jack & The Green Sprouts, Inc., MARCS-CMS 697257 (March 19, 2025).
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jack-green-sprouts-inc-697257-03192025

FDA warning letter to Jimmy John's Franchise, LLC, MARCS-CMS 599962 (February 21, 2020).
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jimmy-johns-franchise-llc-599962-02212020

USDA FSIS

USDA finalizes rule to require labeling of mechanically tenderized beef (May 13, 2015).
https://www.fsis.usda.gov/news-events/news-press-releases/usda-finalizes-rule-require-labeling-mechanically-tenderized-beef

FSIS Petition 16-03, National Chicken Council.
https://www.fsis.usda.gov/federal-register/petitions/establish-labeling-requirements-not-ready-eat-stuffed-chicken-products

FSIS final response to Safe Food Coalition Petition 16-04, safe handling instructions (May 31, 2022).
https://www.fsis.usda.gov/sites/default/files/media_file/2022-06/16-04-Final-Response-05312022.pdf

CDC and the open outbreaks

Taormina, Beuchat & Slutsker, Emerging Infectious Diseases, vol. 5, no. 5 (1999).
https://wwwnc.cdc.gov/eid/article/5/5/99-0503_article

CDC press release, Sprouts: Not a Healthy Food for Everyone (August 9, 1999).
https://www.cdc.gov/media/pressrel/r990809.htm

CDC, Multistate Outbreak of *Salmonella* Enteritidis Infections Linked to Bean Sprouts (Final Update, January 23, 2015).
https://archive.cdc.gov/www_cdc_gov/salmonella/enteritidis-11-14/index.html

CDC investigation notice, alfalfa sprouts.
https://www.cdc.gov/ecoli/outbreaks/alfalfa-sprouts-08-26/index.html

CDC investigation notice, broccoli sprouts.
https://www.cdc.gov/salmonella/outbreaks/broccoli-sprouts-09-26/index.html

CDC, When People Got Sick — illness onset dates, broccoli sprouts outbreak.
https://www.cdc.gov/salmonella/outbreaks/broccoli-sprouts-09-26/timeline.html

FDA outbreak investigation, sprouts, August 2026.
https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-shiga-toxin-producing-e-coli-salmonella-sprouts-august-2026

FDA outbreak investigation, Salmonella, sprouts, September 2026. https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-sprouts-september-2026

German Federal Institute for Risk Assessment (BfR), EHEC outbreak 2011 — Robert Koch Institute figures and the HUS record. https://www.bfr.bund.de/en/ehec_outbreak_2011-186689.html

European Food Safety Authority, task force report on the E. coli O104:H4 outbreaks in Germany and France (July 5, 2011). https://www.efsa.europa.eu/en/press/news/110705

Retailer and chain decisions

Walmart, October 2010. https://www.barfblog.com/2012/02/walmart-stopped-selling-raw-sprouts-over-a-year-ago-for-food-safety-reasons-why-havent-others/

Jason's Deli and the wider retail retreat, January 2012 (NPR). https://www.npr.org/sections/thesalt/2012/01/27/145922622/from-health-food-to-health-risk-sprouts-slip-off-the-menu

Erbert and Gerbert's, February 2012. https://www.prnewswire.com/news-releases/erbert-and-gerberts-sandwich-shops-remove-alfalfa-sprouts-from-menu-139528153.html

Kroger, October 22, 2012 (Food Safety News). https://www.foodsafetynews.com/2012/10/kroger-to-stop-selling-sprouts/

Food Safety News, CDC declares *Salmonella* outbreak linked to sprouts over (March 1, 2023) — SunSprout Enterprises alfalfa sprouts, 63 ill in eight states. https://www.foodsafetynews.com/2023/03/cdc-declares-salmonella-outbreak-linked-to-sprouts-over/

Petitioner's prior statements

William Marler, Two Sprout Outbreaks Are Open Right Now and Seventy-Seven People Are Sick, Marler Blog (September 11, 2026). https://www.marlerblog.com/case-news/two-sprout-outbreaks-are-open-right-now-and-seventy-seven-people-are-sick-fda-has-told-high-risk-consumers-to-stay-away-from-raw-sprouts-since-1998-and-not-one-word-of-that-warning-appears-on-the-pa/

Submission

FDA electronic citizen petition docket, FDA-2013-S-0610. https://www.regulations.gov/document/FDA-2013-S-0610-0003