

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: October 12, 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](#) (petition docket number to be assigned)

Re: Citizen Petition to Require a Warning Statement on Cheese Made From Unpasteurized Milk, and to Complete the Reevaluation of the 60-Day Aging Requirement Announced in 2013

The undersigned submits this petition under sections 201(n), 403(a)(1) and 701(a) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.30, and requests that the Commissioner of Food and Drugs amend 21 CFR 101.17 to require a warning statement on cheese made from unpasteurized milk, and complete the reevaluation of the 60-day aging requirement that this agency announced in 2013.

Twenty-eight years ago this agency required a warning on the label of unpasteurized juice. Twenty-five years ago it required a safe handling statement on shell eggs. Both requirements sit in the same regulation this petition asks the agency to amend, and both were adopted because of an outbreak record. Unpasteurized milk may not be shipped across state lines in a bottle. It may be shipped as cheese, on the strength of a 60-day aging provision written in the 1940s that the agency's own science has since found does not reliably kill the pathogens it was presumed to control, and can, for soft-ripened cheese, increase risk rather than reduce it. The label says nothing.

A. ACTION REQUESTED

The petitioner requests that the Commissioner take the following actions.

1. Require a prescribed warning statement. Amend 21 CFR 101.17 by adding a new paragraph requiring that the label of any cheese or cheese product made from milk that



has not been pasteurized, or subjected to an equivalent validated process to reduce pathogens, bear the following statement:¹

WARNING: This product is made from unpasteurized (raw) milk and may contain harmful bacteria that can cause serious illness in children, older adults, pregnant women, and persons with weakened immune systems.

2. Prescribe the words rather than the elements. The agency concluded in the juice rulemaking that a prescribed statement produces uniform comprehension and removes the drafting judgment from the regulated firm. The same reasoning applies here, and the words above are modeled on the juice warning already codified at 21 CFR 101.17(g)(2).

3. Prescribe placement and prominence. Require, as 21 CFR 101.17(g)(4) through (g)(6) do 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 in bold type, and that the statement, when on a label, be set off in a box by use of hairlines. The petitioner further requests that the statement appear in type of a size and contrast sufficient to be read under customary conditions of purchase.

4. Reach cut-to-order cheese, imported cheese and online sales. Provide that the requirement applies to domestic and imported cheese alike; that cheese cut, wrapped or sold at a service counter without a manufacturer's label may satisfy the requirement by a sign or placard at the point of sale bearing the same statement in the same form; and that a seller offering the cheese online display the statement on the product page, where the buyer will see it before completing the purchase, and, where the product images on that page do not show the statement legibly, post it separately in text. A buyer online cannot turn the package over; the cheese in the September 2026 outbreak was sold online as well as in stores. Cheese sold from a service counter carries no manufacturer label at all, and that is a substantial share of how this product reaches consumers.

5. Exempt product that has been made safe, and product not sold at retail as shipped. Provide that the statement is not required where the milk has been pasteurized or the cheese has been subjected to a process validated to achieve a pathogen reduction equivalent to pasteurization, and that cheese not for distribution to retail consumers in the form shipped is exempt provided the absence of such processing is disclosed in the documents accompanying the shipment. That structure is taken from 21 CFR 101.17(g)(3) and (g)(7) and requires no new drafting.

6. Complete the reevaluation of the 60-day aging requirement. Within one year, publish either a proposed rule addressing the 60-day aging requirement in the standards of identity at 21 CFR part 133, or a written explanation of why the agency will not, and

¹ 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>.

place it in the public docket.² In 2013 the agency stated that it intended to use the joint risk assessment described below, together with other scientific assessments, in its reevaluation of the existing 60-day aging requirements for cheeses made with raw milk.³ The assessment was completed. The reevaluation has not been published. In the interim, state in guidance whether the 60-day aging period may serve, by itself, as an adequate measure to destroy or prevent the growth of undesirable microorganisms under 21 CFR 117.80(c)(4), and as a validated preventive control under 21 CFR 117.160, for the pathogens described in Grounds V, VII and XIII.

7. Publish the raw milk cheese sampling data the agency already collects. Publish annually, at the sample level, the results of raw milk cheese sampling conducted under the agency's domestic and imported cheese compliance program and under any assignment covering aged raw milk cheese, including the fiscal year 2025 collection of aged raw cow's milk cheese for highly pathogenic avian influenza.⁴ The samples are already pulled and the analyses already performed.

8. Set prompt effective and compliance dates. Make any final rule effective 60 days after publication, permit the statement to be given by sign or placard for the first year as the agency did for juice, and require labels to bear the statement thereafter, so that the requirement is satisfied in the ordinary course of label turnover.

9. Provide for verification. State, in the preamble to any final rule and in the compliance programs under which the agency inspects domestic cheese manufacturers and imported cheese, that investigators are to verify the presence, wording and placement of the statement, and provide that accredited third-party certification bodies conducting food or facility certifications under 21 CFR part 1, subpart M, review it. Labeling review in facility inspections and audits now tends to rest on a loose reading of labeling related to food safety hazards. A warning that no one is assigned to check will be applied unevenly, and the importer and the counter clerk are the parties least likely to know it is required.

10. Act expeditiously. The petitioner requests a response within the 180 days required by 21 CFR 10.30(e)(2).⁵

² 21 CFR part 133 (cheeses and related cheese products), in which the 60-day curing provision appears in the individual standards of identity: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-133>.

³ Notice of availability, Draft Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada (Feb. 11, 2013), stating the agency's intent to use the assessment in reevaluating the existing 60-day aging requirements: <https://www.federalregister.gov/documents/2013/02/11/2013-02960/draft-joint-food-and-drug-administration-health-canada-quantitative-assessment-of-the-risk-of>.

⁴ FDA, Microbiological Surveillance Sampling, listing the FY25 aged raw cow's milk cheese collection and analysis for highly pathogenic avian influenza: <https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling>.

⁵ 21 CFR 10.30 (citizen petitions): <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-10/subpart-B/section-10.30>.

B. STATEMENT OF GROUNDS

I. The petitioner

William D. Marler is the managing partner of Marler Clark, Inc., PS, a law firm whose practice is confined to foodborne illness. He has represented victims of foodborne illness since 1993, including children who developed hemolytic uremic syndrome after consuming unpasteurized dairy products. The petitioner represents a claimant in the 2025 Shiga toxin-producing *E. coli* outbreak linked to aged raw milk cheese from Twin Sisters Creamery in Washington State, which is discussed below and is disclosed here so that the agency may weigh the source of this petition.⁶ The petitioner further represents the family of a child who developed hemolytic uremic syndrome in the September 2026 *E. coli* O26:H11 outbreak linked to Graziers raw milk cheese, discussed in Ground IX, and on October 6, 2026 filed suit on the family's behalf against Sierra Nevada Cheese Company in the United States District Court for the Western District of Michigan. The petitioner also represented families in the 2017 listeriosis outbreak linked to Vulto Creamery raw milk cheese, discussed in Ground IX, and people sickened in the 2010 *E. coli* O157:H7 outbreak linked to Bravo Farms raw milk Gouda, noted in Ground VII.

II. What this petition asks for, and what it does not

This petition does not ask the agency to ban raw milk cheese, to extend the aging period, or to restrict who may buy it. It asks for a sentence on the label. Adults who want cheese made from unpasteurized milk would remain free to buy it, with the information the government already gives them about the same milk in a bottle and about unpasteurized juice in a carton. The request is the smallest intervention available that addresses the problem, and it is the one most consistent with consumer choice, because a choice made without the material fact is not the exercise of a preference. Advocates for raw milk have themselves proposed this remedy. A 2017 citizen petition asked the agency to permit raw milk and raw milk products in interstate commerce under a warning label and safe handling instructions, citing the juice warning at 21 CFR 101.17(g) as precedent. Docket No. FDA-2017-P-2626. The petitioner has been unable to determine whether the agency responded to that petition. Dairy processors opposed that petition on the ground that a warning label alone does not adequately protect consumers. That is not a disagreement about whether consumers should be told. It is a disagreement about whether telling them is enough, and it is why this petition asks both for the statement and for the completed reevaluation in item 6.

III. Cheese is the route by which unpasteurized milk lawfully enters interstate commerce

Since 1987 the agency has prohibited the delivery into interstate commerce of milk and milk products in final package form for direct human consumption unless the product has

⁶ Washington State Department of Health, 2025 outbreak of Shiga toxin-producing *E. coli* infections linked to Twin Sisters Creamery aged raw milk cheese: <https://doh.wa.gov/you-and-your-family/illness-and-disease-z/foodborne-illness/outbreaks/2025-outbreak-shiga-toxin-producing-e-coli-stec-infections-linked-twin-sisters-creamery-aged-raw>.

been pasteurized.⁷ The regulation names its own exception: "except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties." Cheese made from unpasteurized milk is that exception, permitted where the cheese is cured at a temperature not lower than 35 degrees Fahrenheit for at least 60 days under the standards of identity.⁸ The 60-day rule is therefore not a detail of cheese making. In the regulation's own words it is the alternative to pasteurization, and it is the entire legal basis on which unpasteurized milk crosses state lines in a form people eat. The exception is broad enough to outlast a court order. A permanent injunction obtained against the producer later linked to two of the outbreaks described in Ground IX imposed restrictions on its interstate distribution of raw milk and raw kefir, but, as the agency's own outbreak records note, the injunction did not cover the producer's aged raw cheese. FDA, CORE Incident No. 1215 records (Feb. 2024) (redacted agency records).

IV. The precedent for the requested label is exact, and it is in the same regulation

In 1998 the agency required a warning statement on packaged juice that has not been processed to prevent, reduce or eliminate pathogens, in the words now codified at 21 CFR 101.17(g): a capitalized, bolded WARNING advising that the product has not been pasteurized and may contain harmful bacteria that can cause serious illness in children, the elderly and persons with weakened immune systems.⁹ The agency adopted that warning while it was still developing the juice hazard analysis rule, as an interim measure, on two findings: that untreated juice had caused outbreaks of serious illness, including a death, and that consumers were largely unaware that a product they regarded as healthful could carry pathogens. It rejected the argument that labeling juice "unpasteurized" was warning enough, because that word tells the consumer what was not done to the product and nothing about the risk.¹⁰ Both findings apply to cheese made from unpasteurized milk, and the second applies with more force, because on this product the absence of pasteurization is presented as a virtue. The requested statement departs from the juice wording in one respect: it names pregnant women. In 1998 the agency declined to add pregnant women to the juice warning because there was no evidence that pregnant women were at greater risk from the pathogens associated with juice, and because *Listeria* had not been identified in the documented juice illnesses. 63 FR 37030, at 37045 (response to comment 51). *Listeria monocytogenes* is the hazard the joint risk assessment modeled for this product. The reason the agency gave for leaving pregnant women out of

⁷ 21 CFR 1240.61 (mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption): <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1240/subpart-D/section-1240.61>.

⁸ See, for example, 21 CFR 133.182 (soft ripened cheeses), one of the individual standards in which the 60-day curing provision appears: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-133/subpart-B/section-133.182>.

⁹ Food labeling: warning and notice statement; labeling of juice products, final rule, 63 FR 37030 (July 8, 1998): <https://www.govinfo.gov/content/pkg/FR-1998-07-08/html/98-18287.htm>.

¹⁰ Food labeling: warning and notice statement; labeling of juice products, final rule, 63 FR 37030, at 37031-37034 (July 8, 1998), setting out the outbreak record, the agency's finding from its consumer research that consumers were largely unaware of the hazard, and the agency's response (comment 11) to the argument that labeling juice as "pasteurized" or "unpasteurized" would be sufficient: <https://www.govinfo.gov/content/pkg/FR-1998-07-08/html/98-18287.htm>.

the juice warning is the reason to include them here. The American Academy of Pediatrics put figures to that reason on October 5, 2026, in a policy statement on the consumption of unpasteurized milk and milk products by pregnant women and children, issued jointly by its Committee on Infectious Diseases and its Committee on Nutrition.¹¹ The Academy reports that listeriosis occurs in pregnancy at 12 to 14 times the rate in the general population, that it ends in miscarriage or stillbirth in one affected pregnancy in five, and that 68 percent of liveborn infants are infected, of whom about one in four dies. The Academy attributes the standing medical advice that pregnant women avoid unpasteurized milk and soft cheese to that association. A warning that names pregnant women tells them on the package what their physicians tell them in the office.

The same regulation carries a second precedent. In December 2000 the agency required a safe handling statement on cartons of shell eggs not treated to destroy *Salmonella*, and required refrigerated storage and display at retail, because of the number of outbreaks and deaths associated with shell eggs.¹² Two categories of raw agricultural product, two mandatory statements, both in section 101.17, both adopted on an outbreak record. A third belongs there.

V. The agency's own risk assessment says the risk is not small

The joint quantitative risk assessment prepared by this agency with Health Canada evaluated listeriosis risk from soft-ripened cheese.¹³ Its conclusions are the strongest scientific support for this petition, and they come from the agency itself. The assessment found the risk of listeriosis from a serving of soft-ripened cheese made from raw milk to be approximately 50 to 160 times greater than from a serving of the same cheese made from pasteurized milk.¹⁴ It found that a reduction of roughly six logs, or its equivalent, in the contamination of the milk is necessary to make raw milk cheese as safe from listeriosis as cheese made from pasteurized milk. And it found that for soft-ripened cheeses the 60-day aging requirement can increase the risk of listeriosis rather than reduce it, by allowing more time for the pathogen, if present, to multiply as the cheese ages.¹⁵

¹¹ American Academy of Pediatrics, Committee on Infectious Diseases and Committee on Nutrition, Consumption of Unpasteurized (Raw) Milk and Milk Products by Pregnant People and Children: Policy Statement (Ratner, A.J., A. Sardi and M.R. Corkins, lead authors), *Pediatrics* e2026079036 (published Oct. 5, 2026), doi: 10.1542/peds.2026-079036, at its discussion of the epidemiology of diseases caused by unpasteurized milk and milk products, reporting the incidence of listeriosis in pregnancy and the rates of fetal loss, neonatal infection and neonatal death:

<https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2026-079036/210736/Consumption-of-Unpasteurized-Raw-Milk-and-Milk>.

¹² Food labeling: safe handling statements: labeling of shell eggs; refrigeration of shell eggs held for retail distribution, final rule, 65 FR 76092 (Dec. 5, 2000), establishing 21 CFR 101.17(h):

<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>.

¹³ Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: <https://www.fda.gov/food/risk-and-safety-assessments-food/joint-fda-health-canada-quantitative-assessment-risk-listeriosis-soft-ripened-cheese-consumption>.

¹⁴ Joint FDA/Health Canada risk assessment, interpretive summary:

<https://www.fda.gov/media/90493/download>.

¹⁵ Joint FDA/Health Canada risk assessment, technical report:

<https://www.fda.gov/media/90488/download>.

That last finding is the one that matters most for item 6. On the agency's own analysis the 60-day rule is not merely an incomplete control for one class of these cheeses. It can work in the wrong direction, and it has stood unchanged since the middle of the last century.

VI. The agency said in 2013 that it would reevaluate the rule, took comments on it in 2015, and stopped

When it announced the draft risk assessment for comment in February 2013, the agency stated that it intended to use the assessment, along with other information and scientific assessments covering the different pathogens that can be present in all types of cheeses made from raw milk, in its reevaluation of the existing 60-day aging requirements. It finalized the assessment on August 3, 2015. In the same issue of the Federal Register it published a request for comments and scientific data on cheese manufactured from unpasteurized milk, Docket No. FDA-2015-N-2596, asking among other things whether a 60-day aging period is effective against pathogens other than *Listeria monocytogenes*, whether a performance standard should replace the 60-day aging requirement, and to what extent consumers understand the risk and consider whether a cheese is made from pasteurized or unpasteurized milk when they buy it.¹⁶ Comments were due November 2, 2015, and seventy-five were filed, including comments from cheesemakers, dairy trade associations and consumer organizations.

Eleven years later, no proposed rule, no completed reevaluation and no published explanation has followed. Item 6 asks for one or the other, which is the minimum a member of the public is entitled to when an agency announces a reevaluation, takes public comment on it, and stops.

VII. The agency's own 2015 notice cites research showing that *E. coli* O157:H7 can survive the 60-day rule in cheddar

The 2015 request for comments is more than a procedural marker. In it the agency described the premise of the 60-day rule and then set out the evidence against it. The aging period, the agency wrote, had been presumed to act as a control measure to reduce the risk that pathogens would be present when the cheese was eaten, but the available data raised questions about the safety of the product "even when aged."¹⁷ The agency then cited two peer-reviewed studies for the proposition that *E. coli* O157:H7 can survive a 60-day aging period in a hard cheese such as cheddar,¹⁸ and a 1997 memorandum of a

¹⁶ Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk; request for comments and for scientific data and information, 80 FR 46023 (Aug. 3, 2015), Docket No. FDA-2015-N-2596; the docket records 75 comments: <https://www.federalregister.gov/documents/2015/08/03/2015-18972/understanding-potential-intervention-measures-to-reduce-the-risk-of-foodborne-illness-from>. The final risk assessment was announced in the same issue: <https://www.federalregister.gov/documents/2015/08/03/2015-18960/joint-food-and-drug-administrationhealth-canada-quantitative-assessment-of-the-risk-of-listeriosis>.

¹⁷ 80 FR 46023, at 46023, cited above.

¹⁸ Reitsma, C.J. and D.R. Henning, Survival of Enterohemorrhagic *Escherichia coli* O157:H7 During the Manufacture and Curing of Cheddar Cheese, *Journal of Food Protection* 59(5):460-464 (1996); Schlessler, J.E., et al., Survival of a Five-Strain Cocktail of *Escherichia coli* O157:H7 During the 60-Day Aging Period of Cheddar Cheese Made from Unpasteurized Milk, *Journal of Food Protection* 69(5):990-998 (2006).

subcommittee of the National Advisory Committee on Microbiological Criteria for Foods stating that the scientific literature confirms that pathogens can survive the 60-day aging process for cheeses manufactured from unpasteurized milk.¹⁹ The same notice recorded that of 65 cheese-associated outbreaks in a 2012 review by the Centers for Disease Control and Prevention, 27 involved products made from unpasteurized milk, although such products were less than one percent of dairy consumption.²⁰

Three points follow. First, the evidence that matters is not confined to *Listeria* or to soft-ripened cheese. The agency's own notice identifies *E. coli* O157:H7 as able to survive the 60-day aging period in cheddar, citing laboratory research, and cheddar is the cheese in three of the four outbreaks set out in Ground IX. Second, the rebuttal that the risk assessment addressed only one pathogen in one type of cheese was anticipated by the agency itself, which asked in 2015 whether the 60-day period is effective against other pathogens and whether a performance standard should replace it. Third, the agency has known for at least eleven years, and the federal advisory committee on microbiological criteria for twenty-nine, that the premise of the rule does not hold, and the label has not changed.

The agency's current good manufacturing practice regulation points the same way. It requires that measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity, taken to destroy or prevent the growth of undesirable microorganisms, be adequate under the conditions of manufacture, handling and distribution to prevent the food from being adulterated. 21 CFR 117.80(c)(4). Aging is not on the list. A facility subject to the hazard analysis and risk-based preventive controls requirements must validate the process controls it relies on, and validation means obtaining and evaluating scientific and technical evidence that a control measure, when properly implemented, is capable of effectively controlling the identified hazards. 21 CFR 117.3, 117.160. Many farmstead cheesemakers are qualified facilities exempt from the preventive controls requirements, 21 CFR 117.5(a), but none is exempt from section 117.80(c)(4). The agency has not said whether 60 days of aging, standing alone, is an adequate or validated control for the pathogens it identified in 2015, and its records described in Ground IX show a firm relying on aging to make pathogen-positive milk safe without having shown that it does. Item 6 asks the agency to say. Until it does, the label is the only place the consumer can learn that the cheese was not pasteurized.

The agency's 2015 reading of the evidence is now the reading of the nation's pediatricians as well. The policy statement of the American Academy of Pediatrics cited in Ground IV describes the cheese exception to the 1987 interstate ban, states that aged cheese sold

Both are cited by the agency as references 3 and 4 at 80 FR 46023, and again in the FY 2014-2016 sampling report cited below.

¹⁹ Memorandum from the Chair, Cheese Subcommittee, National Advisory Committee on Microbiological Criteria for Foods, to the Chair of the Committee, Review of Scientific Literature Regarding the Sixty-Day Aging Process for Hard Cheese (Apr. 3, 1997), cited by the agency as reference 5 at 80 FR 46023 and on file in Docket No. FDA-2015-N-2596.

²⁰ 80 FR 46023, at 46023, citing Langer, A.J., et al., Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993-2006, *Emerging Infectious Diseases* 18(3):385-391 (2012).

under it still poses an infection risk, and states that *E. coli* can survive the 60-day aging period, citing the same 2006 cheddar study the agency cited in 2015.²¹

VIII. The agency's own sampling, and the honest reading of it

The agency selected aged raw milk cheese for large-scale sampling in fiscal years 2014 through 2016 because, in its own words, evidence indicated that aging raw milk cheese for 60 days may not eliminate or adequately reduce disease-causing bacteria, thus posing a potential hazard to consumers.²² Of 1,606 samples, 71 percent of them imported and 29 percent domestic, pathogens were detected in 14: three *Salmonella*, ten *Listeria monocytogenes* and one pathogenic Shiga toxin-producing *E. coli* of serotype O111:H8. Generic *E. coli*, which the agency uses as an indicator of insanitary processing conditions, was found in 5.4 percent of samples.²³

The petitioner states the industry's reading of those results because it is a fair one: a pathogen prevalence under one percent is not a catastrophic figure, and the agency concluded that further large-scale sampling was not warranted. The agency refused entry to violative imported raw milk cheese found in that assignment and placed the responsible firms on Import Alert 12-10. Three answers follow. First, this is a ready-to-eat food with no kill step between the sample and the plate, so prevalence translates directly into exposure, and at national consumption volumes a fraction of one percent is a large number of servings, and the rate of outbreaks per unit consumed has been estimated at roughly 150 times greater for products made from unpasteurized milk.²⁴ Second, six of the *Listeria* isolates recovered from cheese collected in 2014 were identical by whole genome sequencing to the isolate from a 2013 human illness, which is the sampling program detecting exactly what it was designed to detect. Third, the decisive evidence is not prevalence at all. It is the outbreak record since.

Prevalence per sample also understates the burden per serving. A 2017 analysis published in the Centers for Disease Control and Prevention's journal estimated that unpasteurized

²¹ American Academy of Pediatrics policy statement, cited above, at its discussion of the agency's 1987 prohibition and the exception for cheese aged 60 days, citing Schlessner, J.E., et al. (2006), cited above. The Academy illustrates the point with the 2010 multistate outbreak of *E. coli* O157:H7 linked to Bravo Farms Dutch Style Gouda, a raw milk cheese sold at retail, in which 38 people in five states were infected, 15 were hospitalized and one developed hemolytic uremic syndrome. CDC, 2010 *E. coli* Outbreak Linked to Cheese (final update, Nov. 24, 2010): https://archive.cdc.gov/www_cdc_gov/ecoli/2010/bravo-farms-cheese-11-24-10.html. The petitioner does not rely on that outbreak as an example of cheese that complied with the 60-day rule. The agency's inspection of the firm from November 4 to December 1, 2010, as quoted in the verified complaint for forfeiture in rem that the United States filed in the Eastern District of California in January 2011, found that the firm lacked the controls necessary to assure that cheese manufactured from raw milk was aged for the minimum requirement of 60 days; the findings quoted in the complaint are reproduced at <https://billmarler.com/blog/carpe-cheese-bravos-raw-milk-cheese-seized-by-the-fda>. The four outbreaks in Ground IX carry no such finding.

²² FDA, FY 2014-2016 Microbiological Sampling Assignment Summary Report: Raw Milk Cheese (Aged 60 Days): <https://www.fda.gov/media/99340/download>.

²³ FDA, constituent update announcing the completed survey (July 2016): <https://www.fda.gov/food/hfp-constituent-updates/fda-shares-completed-survey-and-data-ongoing-sampling-program>.

²⁴ Pew Charitable Trusts, FDA sampling of raw milk cheese reveals contamination, serious risks (Aug. 2016), describing the CDC analysis finding the outbreak rate per unit consumed to be roughly 150 times greater for products made from unpasteurized milk: <https://www.pew.org/en/research-and-analysis/articles/2016/08/04/fda-sampling-of-raw-milk-cheese-reveals-contamination-serious-risks>.

milk, consumed by 3.2 percent of the population, and unpasteurized cheese, consumed by 1.6 percent, accounted for 96 percent of the illnesses caused by contaminated dairy products in the United States from 2009 to 2014, and that unpasteurized dairy products cause 840 times more illnesses and 45 times more hospitalizations than pasteurized products. The consumption figure may understate exposure today: in the September 2026 outbreak, CDC compared case exposures against a FoodNet Population Survey baseline in which 4.9 percent of respondents reported eating raw milk cheese. The same analysis found, and the petitioner notes it because the certification below requires it, that illnesses and hospitalizations from *Listeria monocytogenes* in that period were more often attributed to pasteurized cheese than to unpasteurized cheese.²⁵ The Academy's policy statement makes a related point: contamination after pasteurization can occur, particularly with *Listeria*, which is why it advises pregnant women to avoid soft cheese whether or not the milk was pasteurized.²⁶ Neither point weakens the requested statement. The warning tells the consumer the one fact the agency's own risk assessment found to multiply the per-serving listeriosis risk by 50 to 160.

IX. Four outbreaks in thirty-one months, in cheese that complied with the rule

Each of the following outbreaks involved cheese made from unpasteurized milk and sold in interstate commerce under the 60-day aging provision. None of them has been reported as a case of a producer evading the 60-day rule. They are cases of the 60-day rule doing what the agency's own science, described in Grounds V and VII, predicted. The fourth was announced on September 25, 2026, while this petition was being prepared, and that investigation remains open. The first and third outbreaks were linked to the same producer, Raw Farm, LLC of Fresno, California; the second and fourth involved different producers in different states.

Outbreak	Product	What happened
February 2024, <i>E. coli</i> O157:H7, five states	Raw cheddar cheese	Eleven people infected, five hospitalized, two cases of hemolytic uremic syndrome; seven of the ten people interviewed reported eating the same brand of raw cheddar; the firm withdrew its recall ten days after initiating it ²⁷

²⁵ Costard, S., et al., Outbreak-Related Disease Burden Associated with Consumption of Unpasteurized Cow's Milk and Cheese, United States, 2009-2014, *Emerging Infectious Diseases* 23(6):957-964 (2017): <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5443421/>.

²⁶ American Academy of Pediatrics policy statement, cited above, at its introduction, identifying contamination after pasteurization, especially with *Listeria*, as the basis for the recommendation that pregnant women and organ transplant recipients avoid soft cheeses.

²⁷ FDA, Outbreak Investigation of *E. coli* O157:H7: Raw Cheddar Cheese (February 2024), final update (Mar. 26, 2024), reporting eleven illnesses in five states, five hospitalizations and two cases of hemolytic uremic syndrome; CDC's final investigation update reports that seven of the ten people interviewed reported eating the cheese, and the February 28, 2024 update records that the firm withdrew its recall on February 26, 2024: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-raw-cheddar-cheese-february-2024>.

Outbreak	Product	What happened
October 2025, Shiga toxin-producing <i>E. coli</i> , Washington and Oregon	Aged raw milk cheese, four varieties	Ten cases across two states, nine in Washington and one in Oregon, with one hospitalization among the Washington cases; the state found two outbreak-associated strains, <i>E. coli</i> O103 and <i>E. coli</i> O26, in cheese sampled from a consumer's home and from retail; the state's own notice records that the cheese was aged at least 60 days, as required by law ²⁸
March 2026, <i>E. coli</i> O157:H7, three states	Raw cheddar cheese and raw milk	Nine people infected, three hospitalized, one case of hemolytic uremic syndrome, with over half the illnesses in children under five; of those interviewed, five reported eating the firm's raw cheddar in 2026 and two reported drinking its raw milk in 2025; onsets from September 1, 2025 to February 20, 2026; the firm declined the agency's request for a voluntary recall before recalling on April 2, 2026 ²⁹
September 2026, <i>E. coli</i> O26:H11, nine states	Aged raw milk cheddar (recall covered four cheddar and jack varieties)	Thirteen people infected, eight hospitalized, three cases of hemolytic uremic syndrome; median age five, with over half the illnesses in children age five or younger; all nine people interviewed reported eating the cheese; illnesses began between July 7 and August 26, 2026; ³⁰ the agency contacted the firm on September 24 and the firm recalled every Graziers raw milk cheese the same day; the labels state that the cheese is aged at least 60 days ³¹

²⁸ Washington State Department of Health, Twin Sisters Creamery outbreak page, cited above.
<https://doh.wa.gov/you-and-your-family/illness-and-disease-z/foodborne-illness/outbreaks/2025-outbreak-shiga-toxin-producing-e-coli-stec-infections-linked-twin-sisters-creamery-aged-raw>.

²⁹ CDC, *E. coli* outbreak linked to raw dairy, investigation updates (March and April 2026):
<https://www.cdc.gov/ecoli/outbreaks/rawcheese-03-26/investigation.html>.

³⁰ CDC, Investigation Update: *E. coli* Outbreak, September 2026 (Sept. 25, 2026), reporting thirteen cases in nine states, eight hospitalizations, three cases of hemolytic uremic syndrome, illness onsets from July 7 to August 26, 2026, a median age of five with over half of those sickened age five or younger, and that all nine people interviewed reported eating Sierra Nevada Cheese Company's Graziers raw milk cheese:
<https://www.cdc.gov/ecoli/outbreaks/raw-milk-cheese-09-26/investigation.html>.

³¹ FDA, Outbreak Investigation of *E. coli* O26:H11: Raw Milk Cheese (September 2026) (Sept. 25, 2026), stating that the agency contacted the firm on September 24, 2026 and recommended a recall, and that the firm agreed and initiated a recall of all Graziers raw milk cheeses the same day; the product image accompanying the advisory shows the labels, which state that the cheese is aged at least 60 days (the sharp cheddar, over 120 days): <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o26h11-raw-milk-cheese-september-2026>.

Table 1. Four outbreaks linked to cheese made from unpasteurized milk, February 2024 to September 2026. Case counts are as published by the investigating agencies; the September 2026 counts are as of September 25, 2026, and that investigation remains open.

The third is also the clearest demonstration of what the present regulatory structure can and cannot do. The agency asked for a recall and was refused (it asked the firm on March 13, 2026 to decide within 24 hours, and the firm declined the next day), the recall came two and a half weeks later, and members of the Congressional Food Safety Caucus urged the agency and the firm to remove the products from the market and signaled openness to strengthening the agency's mandatory recall authority.³² A warning label would not have prevented that outbreak. It would have told the parents of the children who were hospitalized what they were buying. In the same investigation the agency analyzed 19 samples of the firm's raw cheddar and found *E. coli* O157:H7 in one. That strain did not match the outbreak but matched illnesses in a separate 2025 outbreak, and the positive cheese had not been shipped. The agency also held mandatory recall authority under section 423 of the Act, 21 U.S.C. 350l. Even so, the interval between the first illness and the recall was seven months.

The agency's own records of that investigation show why. Its health hazard evaluation found that the firm followed a policy of diverting raw milk that had tested positive for human pathogens into the production of aged raw cheddar, and concluded that the firm's aging process "does not guarantee pathogen elimination." The inspectional observations the agency issued to the firm in April 2026 recorded that the firm had used raw milk that tested positive for pathogens to make raw cheese; that the firm's own testing had found pathogens in batches of cheese after aging was complete, including batches made from milk that first tested negative; and that the firm had not shown that its aging process controls or eliminates pathogens. The agency's summary of those observations states the point directly: the aging process "does not control pathogens in the raw cheddar cheese products." Inspectional observations are not final agency determinations, and the aging periods in these records are redacted; the petitioner does not suggest that the firm's cheese was aged for less than 60 days. The lesson does not depend on it. A rule that treats aging as an alternative to pasteurization invites exactly what the agency found here: sending contaminated milk to the cheese vat on the assumption that time will make it safe. FDA, Health Hazard Evaluation No. 11494 (Apr. 17, 2026); FDA, CORE Executive Incident Summary, CARA No. 1369 (June 18, 2026) (redacted agency records).

The fourth arrived while this petition was being prepared. On September 25, 2026, the Centers for Disease Control and Prevention and this agency announced a multistate outbreak of *E. coli* O26:H11 infections linked to Graziers grass-fed raw milk cheese made by Sierra Nevada Cheese Company of Willows, California: thirteen people in nine states, eight of them hospitalized, three with hemolytic uremic syndrome, and over half of them children age five or younger. The first illness began on July 7. The agency contacted the firm on September 24, eleven weeks later, and the firm recalled every Graziers raw milk cheese the same day. That interval is ordinary for an outbreak investigation, and it is the

³² Congressional Research Service, Food and Drug Administration (FDA) Response to a Raw Dairy Toxic *E. coli* Outbreak, IN12681 (Apr. 2026): <https://www.everycrsreport.com/reports/IN12681.html>.

interval during which the label is the only warning a parent will see. The cheese was sold nationwide, in stores and online, in retail packages and in five-pound loaves to food service customers and wholesalers, and the agency has told retailers that repackaged it for individual sale not to sell it.³³ The agency also warned that the cheese has a long shelf life and told consumers who had stored it without its original packaging to throw it away. Aged cheese stays in refrigerators for months after a recall, and the label is the only warning that stays with it. A five-pound loaf cut and re-wrapped at a service counter carries no manufacturer's label at all, which is the case item 4 addresses. The serogroup, O26, is the one Washington found in the Twin Sisters cheese eleven months earlier. Across the four outbreaks, 43 people have been sickened, 17 hospitalized and at least six have developed hemolytic uremic syndrome, in outbreaks linked to cheese that complied with the 60-day rule; the agency attributes three of the 43, all in the March 2026 outbreak with onsets in September 2025, to the firm's raw milk rather than its cheese.

Whatever the source of contamination at each producer, the rule permitted every one of these cheeses to be sold, and the label told no one anything.

The record before that window points the same way. In 2017 a soft, washed-rind raw milk cheese made in New York was linked to a multistate listeriosis outbreak: eight people infected in four states, all eight hospitalized, one of them a newborn, and two dead.³⁴ A soft, surface-ripened raw milk cheese is the class the joint risk assessment modeled, and the outcome was the one it predicted.

X. The burden falls on children

Over half the illnesses in the March 2026 outbreak, which included early illnesses the agency attributes to the firm's raw milk rather than its cheese, were in children under five, and over half the people sickened in the September 2026 outbreak are children age five or younger; the median age in that outbreak is five, and three of the thirteen have hemolytic uremic syndrome. In the March 2026 outbreak the median age was two, and the youngest patient was one year old. FDA, CORE Executive Incident Summary, CARA No. 1369 (June 18, 2026). A child with a Shiga toxin-producing *E. coli* infection may develop hemolytic uremic syndrome, which is acute kidney failure, and which in the petitioner's experience means dialysis, transfusions, and in the worst cases stroke, colectomy or death, followed by decades of monitoring for chronic kidney disease. The people making the purchasing decision in these cases are parents, and the warning statement requested here is addressed to them. When the agency wrote the juice warning it noted that the median age of the people sickened in the *E. coli* O157:H7 juice outbreak

³³ FDA, Outbreak Investigation of *E. coli* O26:H11: Raw Milk Cheese (September 2026), cited above, stating that the cheese was sold at retailers nationwide and online and to food service customers and wholesalers in 5-pound loaves, and that retailers that received recalled product and repackaged it for individual sale should not sell it; the onset dates are from the CDC investigation update, cited above: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o26h11-raw-milk-cheese-september-2026>.

³⁴ CDC, 2017 Outbreak of *Listeria* Infections Linked to Soft Raw Milk Cheese Made by Vulto Creamery (final update, May 3, 2017), reporting eight people infected in four states, all eight hospitalized, one illness in a newborn, and two deaths, in Connecticut and Vermont; the firm recalled all lots of its raw milk cheeses on March 10, 2017: https://archive.cdc.gov/www_cdc.gov/listeria/outbreaks/soft-cheese-03-17/index.html.

it was responding to was five, and it declined for that reason to narrow the word "children."³⁵ The median age in the September 2026 cheese outbreak is five.

The physicians who treat those children have said the same. The American Academy of Pediatrics policy statement cited in Ground IV reports that of the 675 illnesses in outbreaks linked to unpasteurized milk from 2013 to 2018, nearly half were in people under 20 and 14 percent were in children under five, with ten cases of hemolytic uremic syndrome, and it notes that young children are at increased risk of that complication from *E. coli* O157, which can be fatal.³⁶ The Academy's recommendations are addressed to the same people as the warning requested here. It advises pediatricians and obstetricians to counsel families to choose only dairy products labeled as pasteurized, and it encourages pediatricians to work with public health officials for restrictions on raw milk sales, naming warning labels as its example of such a restriction.³⁷ Counsel to buy only what is labeled pasteurized works only if the label distinguishes the product, and the agency has conceded, as Ground XI shows, that aged raw milk cheese is not required to be labeled as such. The statement requested here is the label that makes the pediatrician's advice usable in a grocery aisle.

XI. The current label does not tell the consumer what the agency intends

Cheese made from unpasteurized milk is frequently labeled as such, but the statement appears as an ingredient description or as a marketing claim, in the same type as everything else on the package, and it conveys craft rather than hazard. The package in the September 2026 outbreak calls the product grass-fed raw milk cheese and states that it is aged at least 60 days, which tells the buyer that the cheese complied with the rule and nothing about what the rule does not do. The label of the raw cheddar in the March 2026 outbreak, as transcribed in the agency's health hazard evaluation, reads "NEVER WARMED ABOVE 102F (TRULY RAW)" and "MADE WITH WHOLE RAW MILK." On that label the absence of pasteurization is the selling point, and nothing is said about risk. Nothing on the label tells a pregnant woman, the parent of a toddler or a person on immunosuppressive therapy that this is a product the government advises them not to eat. Cheese cut at a service counter carries nothing at all. In the 2025 Twin Sisters outbreak, the Washington State Department of Health advised that people who are pregnant, newborns, people 65 and older, and people with weakened immune systems avoid any cheese made with unpasteurized milk unless it is heated to 165 degrees Fahrenheit or until steaming hot, and noted that some of the recalled cheese had been repackaged by grocery stores so that the original label might not be present. In 1998 the agency declined to extend the juice warning to unpackaged juice sold for immediate consumption, consistent with its practice that food labeling regulations do not reach unpackaged food unless they say so. 63 FR 37030, at 37037-38 (response to comment 24). Cheese cut and re-wrapped at a service counter is different: it is sold in a package for

³⁵ 63 FR 37030, at 37044 (response to comment 49), cited above.

³⁶ American Academy of Pediatrics policy statement, cited above, at its discussion of the epidemiology of diseases caused by unpasteurized milk and milk products, summarizing Koski, L., et al., Foodborne illness outbreaks linked to unpasteurised milk and relationship to changes in state laws—United States, 1998-2018, *Epidemiology and Infection* 150:e183 (2022), doi: 10.1017/S0950268822001649.

³⁷ American Academy of Pediatrics policy statement, cited above, at its conclusions.

later consumption, often from a manufacturer's loaf that could have carried the statement, which is why item 4 provides for a sign or placard.

The agency publishes that advice itself. Its consumer page on raw milk states that while raw milk puts all consumers at risk, the elderly, immune-compromised people, children and pregnant women are especially vulnerable; that the agency's position is in concert with the Centers for Disease Control and Prevention and the American Academy of Pediatrics; and that since 1987 there have been 143 reported outbreaks associated with raw milk and raw milk products, a figure the agency has published since at least 2011.³⁸ The agency has also conceded, in the published instructions for its own 2025 sampling assignment, that aged raw cow's milk cheese "is not required to be labeled" as such, so that its investigators must identify the product from shipping documents and by asking distributors.³⁹ If the agency's own investigators cannot identify the product from its label, a parent in a grocery aisle cannot be expected to. The Academy's October 2026 policy statement shows how far the assumption of a label reaches. In describing the cheese exception to the 1987 interstate ban, the Academy writes that the exception requires the cheese to be aged 60 days and "clearly labeled as unpasteurized."⁴⁰ The agency's own sampling instructions, quoted above, say the opposite: the product is not required to be labeled as such. When the nation's pediatricians assume a label that the law does not require, the case for requiring one has been made for the agency.

The two states in which the Ground IX producers operate have stopped at the bottle. California has required since 1991 that raw milk and raw milk products bear a boxed WARNING that they may contain disease-causing microorganisms, naming the groups at highest risk, among them pregnant women, and it deems a product without the warning misbranded; but its definition of a raw milk product expressly excludes cheese ripened or cured at least 60 days.⁴¹ Washington has required a warning on containers of raw milk sold to consumers since 1997, and the rule by its terms applies to containers of raw milk, not to cheese.⁴² The producers in all four outbreaks in Ground IX are in those two states. Under state law none of their cheese had to carry a warning, and under federal law none

³⁸ FDA, Food Safety and Raw Milk (consumer page, content current as of March 5, 2024):

<https://www.fda.gov/food/buy-store-serve-safe-food/food-safety-and-raw-milk>.

³⁹ FDA, Microbiological Surveillance Sampling: FY25 Aged Raw Cow's Milk Cheese Collection and Analysis for HPAI (Dec. 30, 2024), Questions and Answers, asking how field staff will identify the product "when it is not required to be labeled": <https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy25-aged-raw-cows-milk-cheese-collection-and-analysis-hpai>.

⁴⁰ American Academy of Pediatrics policy statement, cited above, at its discussion of guidelines for sales of unpasteurized milk and milk products by this agency and the states. The Academy's description of the exception is otherwise accurate: 21 CFR 1240.61 and part 133 require 60 days of aging and no statement on the label.

⁴¹ California Code of Regulations, title 17, section 11380 (operative 1991), subsections (a), (c)(2) and (e): <https://www.law.cornell.edu/regulations/california/17-CCR-11380>. The California Department of Public Health describes the requirement on its raw milk page: <https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/RawMilkandRawDairyProductsRiskandRecommendations.aspx>.

⁴² Washington Administrative Code 16-101-800, raw milk warning labels (adopted Sept. 11, 1997, WSR 97-19-045), which by its terms applies to containers of raw milk intended for sale to consumers: <https://lawfilesext.leg.wa.gov/law/WACArchive/2020/hm/WAC%20%2016%20%20TITLE/WAC%20%2016%20-101%20%20CHAPTER/WAC%20%2016%20-101%20-800.htm>.

of it did. California's exclusion rests on the assumption the agency's own science has undermined: that 60 days of aging makes the warning unnecessary.

In 1998 the agency considered and rejected the argument that labeling juice as unpasteurized was warning enough, because the word describes the treatment the product did not receive and says nothing about the risk.⁴³ The words "raw milk cheese" do the same, and on this product they are a selling point. The label is where the agency's advice would reach the person making the decision.

XII. The legal authority is settled

A food is misbranded if its labeling is false or misleading in any particular.⁴⁴ Labeling is misleading not only by what it says but by its failure to reveal facts material in light of representations made, or material with respect to consequences which may result from use of the article under the conditions prescribed in the labeling or under customary conditions of use.⁴⁵ That the milk was not pasteurized, and that the product may therefore carry pathogens causing serious illness in identified groups, is a material fact with respect to the consequences of use. The agency has authority to issue the regulation under section 701(a).⁴⁶ The agency also holds independent authority under section 361 of the Public Health Service Act, which is the authority underlying 21 CFR 1240.61 itself.⁴⁷

The requested statement is also the kind of compelled commercial disclosure the courts have sustained. A requirement that a seller disclose purely factual and uncontroversial information about its product is reviewed under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and the United States Court of Appeals for the District of Columbia Circuit, sitting en banc, has held that this standard applies to disclosures that serve governmental interests beyond the prevention of deception. *American Meat Institute v. U.S. Department of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). That the milk was not pasteurized is a fact. That unpasteurized dairy products may contain pathogens is the agency's settled public position, the text of California's own warning and, as of October 5, 2026, the restated position of the American Academy of Pediatrics, whose policy statement collects the concurring positions of the American Medical Association, the American Public Health Association, the American College of Obstetricians and Gynecologists and the World Health Organization, among others.⁴⁸ The juice and shell egg statements in the same regulation have stood for more than a quarter century. The

⁴³ 63 FR 37030, at 37034 (response to comment 11), cited above.

⁴⁴ Federal Food, Drug, and Cosmetic Act section 403(a)(1), 21 U.S.C. 343(a)(1):
<https://www.law.cornell.edu/uscode/text/21/343>.

⁴⁵ Federal Food, Drug, and Cosmetic Act section 201(n), 21 U.S.C. 321(n):
<https://www.law.cornell.edu/uscode/text/21/321>.

⁴⁶ Federal Food, Drug, and Cosmetic Act section 701(a), 21 U.S.C. 371(a):
<https://www.law.cornell.edu/uscode/text/21/371>.

⁴⁷ Public Health Service Act section 361, 42 U.S.C. 264:
<https://www.law.cornell.edu/uscode/text/42/264>.

⁴⁸ American Academy of Pediatrics policy statement, cited above, at its discussion of recommendations from national and international organizations, listing the American Medical Association, the American Veterinary Medical Association, the International Association for Food Protection, the National Environmental Health Association, the American Public Health Association, the American College of Obstetricians and Gynecologists, the World Health Organization and this agency as having endorsed the consumption of only pasteurized milk and milk products.

Supreme Court has described the Zauderer standard as reaching purely factual and uncontroversial disclosures that are not unjustified or unduly burdensome. *National Institute of Family and Life Advocates v. Becerra*, 585 U.S. 755 (2018). The Fifth Circuit has since applied Zauderer to sustain this agency's own required health warnings. *R.J. Reynolds Tobacco Co. v. FDA*, 96 F.4th 863 (5th Cir. 2024), cert. denied, No. 24-189 (U.S. Nov. 25, 2024). The requested statement is a single factual sentence that repeats the agency's own published advice and imposes no burden beyond the printing of a label.

XIII. Avian influenza is a new reason, and a current one

The hazard profile of this product has changed since the 60-day rule was written and since the risk assessment was completed. Highly pathogenic avian influenza H5N1 has circulated in United States dairy herds since March 2024. In December 2024 the agency began a sampling assignment to collect 300 samples of aged raw cow's milk cheese from warehouses and distribution hubs and test them for viable H5N1.⁴⁹ In March 2025 it reported interim results, 96 of the first 110 samples negative by PCR and 14 pending, and stated that final results were expected later that spring.⁵⁰ As of the date of this petition the assignment page has not been updated since December 30, 2024, and no final results have been posted. Item 7 asks for them. The petitioner notes, as the certification below requires, that the interim results detected no H5N1 and that the agency has stated it is not aware of any H5N1 illness from the consumption of aged raw milk cheese.

The research the agency funded to answer the underlying question has been published. A study at Cornell University, supported by the agency and the State of New York and published in *Nature Medicine* in October 2025, found that aging raw milk cheese for 60 days or longer is not, by itself, effective at eliminating viable H5N1: the virus survived through and beyond the 60-day aging period in cheese made at pH 6.6 and 5.8, and was inactivated only in cheese made at pH 5.0 or from heat-treated milk.⁵¹ In the same study, ferrets fed contaminated raw milk became infected, while ferrets fed contaminated raw milk cheese did not. The agency's response has been a recommendation that processors not use milk from infected cows in raw milk products. A recommendation is not a rule, and a rule that rests on 60 days of aging is, on the agency's own funded research, not a control for this virus. That is a further reason to complete the reevaluation requested in item 6, and it is a current one.

⁴⁹ FDA, FY25 Aged Raw Cow's Milk Cheese Collection and Analysis for HPAI, cited above, stating that 300 samples would be collected from warehouses and distribution hubs and that the agency would publicize the findings after all testing and analysis were complete. As of the date of this petition the page shows content current as of December 30, 2024: <https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy25-aged-raw-cows-milk-cheese-collection-and-analysis-hpai>.

⁵⁰ FDA, Investigation of Avian Influenza A (H5N1) Virus in Dairy Cattle, reporting on March 14, 2025 the interim sampling results (96 of the first 110 samples negative by PCR, 14 in progress, final results expected later that spring), summarizing the Cornell University research, and recommending that dairy processors not use milk from infected cows in the production of raw milk products such as raw milk cheese: <https://www.fda.gov/food/alerts-advisories-safety-information/investigation-avian-influenza-h5n1-virus-dairy-cattle>.

⁵¹ H5N1 influenza virus stability and transmission risk in raw milk and cheese, *Nature Medicine* (published Oct. 8, 2025): <https://www.nature.com/articles/s41591-025-04010-0>. The agency's summary of the findings appears on the page cited in the preceding footnote.

XIV. The objections, stated fairly and answered

The first objection is cost to small producers, and it is the most serious one. Many raw milk cheesemakers are small farmstead operations, and a label change is not free. The requested rule answers that in three ways: the statement is a single sentence with no testing, reformulation or process change behind it; the placard option in item 4 allows a retailer to satisfy it without any label at all for cut-to-order cheese; and the compliance dates in item 8 follow the juice model, under which signs and placards were permitted for the first year and labels turned over in the ordinary course. In 1998 the agency estimated the cost of compliance at about \$100 per firm by sign or placard and about \$1,000 by sticker. 63 FR 37030, at 37037 (response to comment 22). Much imported raw milk cheese already carries a raw milk disclosure: the European Union requires the words "made with raw milk" on products made from raw milk without heat or other treatment. Regulation (EC) No 853/2004, Annex III, Section IX, Chapter IV. That disclosure describes the process rather than the risk, which is the gap the agency identified in 1998, but it shows that a statement on the label is an ordinary cost of selling this product.

The second objection is that consumers who buy raw milk cheese already know it is raw. Some do. The person who buys it is not always the person who eats it, the cheese board at a party carries no label, and the pregnant guest did not make the purchase. The juice warning answered the identical objection in 1998. The agency's consumer research found the same thing: even participants who said they would keep drinking untreated juice said the warning would influence whether they gave it to their children. 63 FR 37030, at 37035 (response to comment 14).

The third objection is that a warning statement is the first step toward prohibition. This petition is evidence to the contrary. It asks for disclosure and for the completion of a scientific reevaluation the agency itself announced, and it asks for nothing else. If that reevaluation concludes that the 60-day rule is adequate for particular cheese types, the label requested here remains appropriate, because the consumer's interest in knowing is not contingent on the outcome. The petitioner notes, so that the objection is answered on a full record, that the American Academy of Pediatrics does endorse a prohibition. Its October 2026 policy statement endorses a ban on the sale or distribution of unpasteurized milk and milk products throughout the United States, including fresh, soft and soft-ripened raw milk cheeses, and in the meantime encourages pediatricians to advocate for restrictions on raw milk sales "such as warning labels."⁵² This petition asks for the warning label. The ban is the Academy's position, not the petitioner's, and the agency can grant everything requested here without reaching it.

The fourth objection is that this is a matter for the states. It is not. The 60-day exception is a federal rule, and the product it permits crosses state lines under federal authority. A state may require a warning on cheese sold within its borders, but none has: a consumer in one state buying cheese made in another is protected by neither state's labeling law as written. And the two states in which those producers operate have not reached this product: as Ground XI shows, California's warning excludes 60-day cheese by definition and Washington's applies to containers of milk. The cheese in the four outbreaks in

⁵² American Academy of Pediatrics policy statement, cited above, at its conclusions.

Ground IX crossed state lines without a warning required by the state in which it was made.

The fifth objection is warning fatigue, and the petitioner does not dismiss it. The answer is that this warning is not proliferating across the dairy case. It attaches to a narrow category defined by the absence of the one process that makes the rest of the category safe, which is the same line the agency drew for juice. Untreated juice was then less than 5 percent of juice consumed, and the agency's focus group participants were reassured to learn that the warning would apply only to a narrow and distinctive segment of products. 63 FR 37030, at 37043 (response to comment 44). The agency answered the same objection in 1998, when commenters said the juice warning would start a trend toward warnings on all foods, by noting that it had used its authority under sections 201(n) and 403(a)(1) to require warnings only rarely, and only where the statutory criteria are met.⁵³ In the twenty-eight years since, the shell egg statement is the only one it has added to the section. The sixth objection is that a warning licenses contaminated product or shifts responsibility to the consumer. The agency answered that in 1998 as well: the warning does not relieve a manufacturer of its obligations, and a product that contains harmful bacteria remains adulterated and unlawful whether or not it bears the statement. 63 FR 37030, at 37033 (responses to comments 8 and 9).

XV. What this would cost, and what the status quo costs

The cost of the requested label is the design of one sentence and the printing of labels reprinted anyway. Against that stands a hospitalized child, a recall that by the firm's own account affected approximately 1.5 million dollars of its product,⁵⁴ and the recurring expense to every producer in the category of being associated with outbreaks they had no part in.

XVI. Conclusion

This agency prohibits unpasteurized milk in interstate commerce, permits it in cheese on the strength of a 60-day aging provision it calls an alternative to pasteurization, published a risk assessment finding that the provision can increase risk for an entire class of these cheeses, wrote in 2015 that *E. coli* O157:H7 can survive the provision in cheddar and took public comment on replacing it, funded research finding that the provision does not eliminate H5N1, and has finished none of it. In the meantime four outbreaks in thirty-one months have been linked to cheese that complied with the rule, the most recent announced on September 25, 2026 with over half of its victims age five or younger, and the label says nothing. On October 5, 2026 the American Academy of Pediatrics said in a policy statement that aged cheese sold under the exception still poses an infection risk, and named warning labels among the measures to pursue. Everything needed to write this rule is in the agency's files. The petitioner asks for the sentence, and for the reevaluation the agency promised.

⁵³ 63 FR 37030, at 37035 (response to comment 17), cited above.

⁵⁴ Congressional Research Service, IN12681, cited above, reporting that the firm stated the April 2026 recall affected approximately 1.5 million dollars of its product:
<https://www.everycrsreport.com/reports/IN12681.html>.

C. ENVIRONMENTAL IMPACT

The petitioner claims a categorical exclusion under 21 CFR 25.30(k), which covers the establishment by regulation of labeling requirements for marketed articles where there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes. The action requested is a labeling requirement; it does not increase the use of cheese made from unpasteurized milk or change its intended use, and it does not individually or cumulatively have a significant effect on the human environment. To the petitioner's knowledge, no extraordinary circumstances exist.⁵⁵ Items 6 and 7 request the publication of a proposed rule or written explanation and of existing data, and any rulemaking that follows will carry its own environmental review.

D. ECONOMIC IMPACT

Information on economic impact will be submitted upon request of the Commissioner in accordance with 21 CFR 10.30(b). The petitioner notes that the agency prepared an economic analysis for the unpasteurized juice warning at 21 CFR 101.17(g) and for the shell egg safe handling statement at 21 CFR 101.17(h), and that both are available to the agency as benchmarks for a labeling requirement of the same form.

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

cc:

⁵⁵ 21 CFR part 25 (environmental impact considerations; categorical exclusions):
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-25>.

The Honorable Secretary of Health and Human Services
Commissioner of Food and Drugs, U.S. Food and Drug Administration
Deputy Commissioner for Human Foods, U.S. Food and Drug Administration
Director, Office of Microbiological Food Safety, Human Foods Program, U.S. Food and Drug Administration
Chief Counsel, U.S. Food and Drug Administration
Executive Secretary, National Conference on Interstate Milk Shipments

Sources cited — Citizen Petition on a Warning Statement for Cheese Made From Unpasteurized Milk

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