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November 4, 2026

The Honorable Bill Cassidy, M.D., Chairman
The Honorable Bernie Sanders, Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC 20510

Re: Botulism in infant formula after Tuesday's election — the gavel changes hands in January and the facts in my June 29 and August 28 letters do not; a request to finish the Senate's work before the 119th Congress adjourns, and an offer to bring the families to your offices

Dear Chairman Cassidy, Ranking Member Sanders, and Members of the Committee:

I have written to this Committee twice about botulism in powdered infant formula: on June 29, to give you credit for S. 272 and to ask for three things, and on August 28, the day after the federal government confirmed by whole genome sequencing that the ByHeart and Nara Organics outbreaks were one contamination that reached two brands through one shared supply of milk.[1] I have had no reply to either letter. I am writing a third time, in the week of an election, because the election changed one thing and left everything else exactly where it was.

What it changed is control. The voters gave the Democratic Party the majority in both chambers of the 120th Congress, which takes office on January 3, 2027, and with it the gavel of this Committee.[2] Chairman Cassidy, you hold that gavel until then. What the election did not change

[1] William D. Marler, *Letter to the Committee on Health, Education, Labor, and Pensions* (June 29, 2026), www.marlerblog.com/files/2026/06/Marler_Senate_HELP_Letter_Letterhead.pdf; William D. Marler, *Senate HELP Committee Follow-Up Letter* (Aug. 28, 2026), www.marlerblog.com/files/2026/08/Senate_HELP_Follow-Up_Letter_8_28_26_WDM.pdf. For the genetic link, see CDC, *Investigation Update on Infant Botulism Outbreak, June 2026* (Aug. 27, 2026) (whole genome sequencing linking a Nara patient sample to a patient sample, product samples and an ingredient sample from the 2025 ByHeart investigation; both formulas made with milk supplied by Organic West Milk and spray dried by Dairy Farmers of America), and FDA, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)* (update of Aug. 27, 2026), www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-powdered-infant-formula-june-2026.

[2] As projected by the Associated Press and the networks in the early hours of November 4, 2026. See NBC News, *Midterms 2026 highlights: Democrats win control of Congress*, www.nbcnews.com/politics/2026-election/live-blog/midterm-election-results-2026-news-trump-live-updates-rcna605763; CBS News, *Live election results for 2026 midterms as Democrats decisively win control of House and Senate*, www.cbsnews.com/live-updates/election-day-

is a single fact in the two letters already in your files. Fifty-two infants were hospitalized with botulism after being fed powdered formula — forty-eight in the ByHeart outbreak, across seventeen states, and four in the Nara outbreak — many of them on ventilators, every one of them treated with an antitoxin the State of California prices at $69,300 a dose.[3] The same organism was sequenced from an infant fed one brand and from the base powder and sealed cans of the other. Federal regulation still requires powdered infant formula to be tested for exactly two organisms, *Cronobacter* and *Salmonella*, and *Clostridium botulinum* is still not one of them.[4] S. 272, which this Committee reported 22 to 0 and the Senate passed by unanimous consent in April, still reaches only those two. None of that was on the ballot.

This has never been a party question, and the record proves it

I want to spend a paragraph on this, because the next two months in Washington will be spent assigning blame for Tuesday, and I would like infant formula kept out of it.

S. 272 was introduced by Gary Peters, a Democrat, and John Hoeven, a Republican, and not one member of this Committee or of the Senate voted against it.[5] H.R. 7867, the broader House bill, was introduced by Rosa DeLauro, a Democrat, and is co-led by Jeff Van Drew, a Republican.[6] The March 2023 letter in which the FDA named *Clostridium botulinum* to the entire powdered formula industry, before the first ByHeart infant became ill, went out under the last administration.[7] Operation Stork Speed, the largest contaminant testing of infant formula this country has ever run, and last Thursday's proposed rule modernizing formula nutrient requirements for the first time in nearly thirty years came from this one, and I have given this administration credit for all three in writing — to this Committee in June and on my own blog the

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2026-midterms/. The terms of the 119th Congress end, and those of the 120th begin, at noon on January 3, 2027. U.S. Const. amend. XX, § 1.

[3] CDC, *Infant Botulism Outbreak Linked to Powdered Infant Formula, November 2025* (outbreak declared over Feb. 26, 2026; page updated Mar. 5, 2026) (48 infants in 17 states, 28 confirmed and 20 probable, all hospitalized), www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html; CDC, *Investigation Update on Infant Botulism Outbreak, June 2026* (Aug. 27, 2026) (four infants in California, Pennsylvania and Washington, all hospitalized and treated with BabyBIG), www.cdc.gov/botulism/outbreaks-investigations/infant-formula-june-2026/investigation.html; California Dep't of Public Health, Infant Botulism Treatment & Prevention Program, *BabyBIG® Fee Schedule* — $69,300 per dose (eff. July 1, 2025), www.cdph.ca.gov/Programs/OLS/CDPH%20Document%20Library/DPH-25-005-BabyBIG_Fee_FP.pdf.

[4] 21 C.F.R. § 106.55(e) (finished-product microbiological testing of powdered infant formula limited to *Cronobacter* spp. and *Salmonella* spp.), www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106/subpart-B/section-106.55.

[5] Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (introduced by Sen. Peters with Sen. Hoeven; reported favorably by the Senate HELP Committee 22–0 on Jan. 15, 2026; passed the Senate with an amendment by unanimous consent, Apr. 28, 2026), www.congress.gov/bill/119th-congress/senate-bill/272.

[6] Infant Formula Safety Modernization Act of 2026, H.R. 7867, 119th Cong. (introduced Mar. 9, 2026, by Rep. DeLauro, with Rep. Van Drew among the original cosponsors; referred to this Committee; Subcommittee on Health legislative hearing Apr. 29, 2026), www.congress.gov/bill/119th-congress/house-bill/7867; text at www.govinfo.gov/content/pkg/BILLS-119hr7867ih/html/BILLS-119hr7867ih.htm.

[7] FDA, *Letter to the Powdered Infant Formula Industry* (Mar. 8, 2023) (signed by the Commissioner of Food and Drugs and the Director of the Center for Food Safety and Applied Nutrition; "Historical associations between powdered infant formula and pathogens such as *Cronobacter* spp., *Salmonella*, and *Clostridium botulinum* should be considered when designing and implementing controls"), www.fda.gov/media/166044/download. The first illness onset in the ByHeart outbreak was December 24, 2023. CDC, supra note 3.

day the nutrient rule was announced.[8] Chairman Cassidy, when you demanded answers from ByHeart in December and from Nara Organics in July, I said publicly that you were right to.[9] Four years ago, when a contaminated plant in Sturgis, Michigan emptied the nation's formula shelves, the House passed the Access to Baby Formula Act 414 to 9, this Senate cleared it by unanimous consent the next day, and the President signed it that Saturday — four days from introduction to law.[10] And thirty-two years ago, a Democratic administration's USDA declared *E. coli* O157:H7 an adulterant in ground beef after the Jack in the Box outbreak, and every Congress and every administration since, of both parties, has left that rule where it was.[11]

For my own part: I raised money for a Democratic presidential candidate in 2008, and I have praised a Republican administration's formula testing in writing to this Committee this year. I have sued formula companies without asking how their executives vote. Nobody has ever accused me of being partisan about a baby on a ventilator, and I am asking this Committee not to be either.

What has happened since August 28

In September, two t-shirts, compressed into the shape of a baby bottle, were hand-delivered to every one of the twenty-three offices on this Committee, and one went to every other member of Congress.[12] They read: For Babies' sake, Test for Botulism in Infant Formula. If one is still on a desk in Dirksen, it still says the whole argument in one line.

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[8] HHS & FDA, *HHS, FDA Announce Operation Stork Speed* (Mar. 18, 2025), www.fda.gov/news-events/press-announcements/hhs-fda-announce-operation-stork-speed-expand-options-safe-reliable-and-nutritious-infant-formula; FDA, *FDA Releases Results from Largest-Ever Testing of Infant Formula in the U.S.* (Apr. 29, 2026); HHS, *Trump Administration Announces First Major Update to Infant Formula Standards in Nearly 30 Years* (Des Moines, Oct. 29, 2026), www.hhs.gov/press-room/fda-updates-infant-formula-standards-first-time-30-years.html; FDA, *Infant Formula Nutrient Requirements*, proposed rule, Docket No. FDA-2026-N-10832, RIN 0910-AJ34 (first of three planned proposed rules; comments due 120 days after Federal Register publication, which the HHS release gives as February 26, 2027), www.federalregister.gov/public-inspection/2026-22273/infant-formula-nutrient-requirements. My letter to this Committee of June 29, 2026, supra note 1, gave the administration credit for Operation Stork Speed and the April testing; see William D. Marler, *Credit Where It Is Due on Formula Nutrients — and a Reminder That Fifty-Two Babies Were Paralyzed by Something Else* (Oct. 29, 2026), www.marlerblog.com/case-news/credit-where-it-is-due-on-formula-nutrients-and-a-reminder-that-fifty-two-babies-were-paralyzed-by-something-else/.

[9] Senate HELP Committee, *Chair Cassidy Raises Concerns on Infant Formula Safety, Impact on Children's Health* (Dec. 2025) (letter to ByHeart requesting answers by Jan. 14, 2026), www.help.senate.gov/rep/newsroom/press/chair-cassidy-raises-concerns-on-infant-formula-safety-impact-on-childrens-health; Senate HELP Committee, *Chairman Cassidy Expands Investigation into the Safety of Infant Formula* (July 2026) (letter of July 15, 2026, to Nara Organics requesting answers, question by question, by July 29, 2026), www.help.senate.gov/rep/newsroom/press/chairman-cassidy-expands-investigation-into-the-safety-of-infant-formula.

[10] Access to Baby Formula Act of 2022, Pub. L. No. 117-129 (H.R. 7791, 117th Cong.) (introduced May 17, 2022; passed the House 414–9 on May 18; passed the Senate without amendment by unanimous consent on May 19; signed May 21, 2022), www.congress.gov/bill/117th-congress/house-bill/7791.

[11] U.S. Dep't of Agriculture, Food Safety & Inspection Service, *Risk Assessment of E. coli O157:H7 in Ground Beef* ("In August 1994, FSIS declared E. coli an adulterant."), www.fsis.usda.gov/node/2003.

[12] William D. Marler, *Two Shirts to Every Office That Can Move This Bill* (Sept. 2026); *Botulism T-Shirts and Four Unanswered Letters Go to Capitol Hill Wednesday and Thursday* (Sept. 2026), www.marlerblog.com/case-news/botulism-t-shirts-and-four-unanswered-letters-go-to-capitol-hill-wednesday-and-thursday/; *The Shirts Have*

The FDA has written to the industry about the organism three times, beginning in March 2023 and most recently on July 13; it has presented an interim test method that is still awaiting validation; it referred the question to an expert group convened by the FAO and WHO, which this summer added botulinum neurotoxin-producing clostridia to its priority hazards for powdered formula; and when it pulled forty-eight samples of milk powder from suppliers to formula makers, it found a gene associated with botulinum toxin in two of them.[13] Last Thursday it proposed a serious nutrient rule. It has not proposed a rule that requires anyone to test formula, or the milk powder it is made from, for the organism that paralyzed these babies.

Later this week I will file with the FDA the citizen petition enclosed with this letter.[14] It asks the Commissioner to add botulinum neurotoxin-producing clostridia to the finished-product testing table at 21 C.F.R. § 106.55(e); to require that each lot of whole milk powder, nonfat dry milk, whey and the other dairy ingredients be tested before it is used, because that is where the organism came in; to require notice to the FDA within one business day of a confirmed positive; to finalize the test method within 180 days; and to require supplier verification and lot-level records that trace each ingredient back to the dryer and the farm. Forty-four parents of twenty-three of these infants are co-petitioners, and so is Stop Foodborne Illness. The FDA's own rules give it 180 days to respond. I will send you the docket number when it is assigned.

The petition matters to this Committee in particular. Everything in it is something Congress can order by statute, or press the agency to do by regulation at a hearing. And S. 272's one-business-day notice duty is drafted to follow the § 106.55(e) list "or any successor regulation," so the day the FDA adds the organism to its own table, the Senate's bill reaches botulism without another

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Been on 77 Committee Desks for a Week. No Markup, No Hearing, No Reply (Sept. 2026), www.marlerblog.com/case-news/the-shirts-have-been-on-77-committee-desks-for-a-week-no-markup-no-hearing-no-reply-and-the-fourteen-families-who-wrote-to-congress-have-heard-nothing-at-all/.

[13] FDA, *Letter to the Infant Formula Industry and Supply Chain Partners* (July 13, 2026), www.fda.gov/media/193534/download; FDA, *Post-Outbreak Response Activities: Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula* (February 2026 surveillance sampling: 48 powdered milk samples from four suppliers to infant formula manufacturers, two positive by PCR for a *Clostridium* (*C. sporogenes*) carrying a gene associated with botulinum toxin; page current as of Sept. 22, 2026), www.fda.gov/food/outbreaks-foodborne-illness/post-outbreak-response-activities-clostridium-botulinum-illnesses-associated-consumption-powdered; Reagan-Udall Foundation for the FDA, *Applying the Science of Infant Formula Safety* (report released Sept. 3, 2026) (interim FDA analytical workflow presented July 13, 2026, validation pending), reaganudall.org/publications/applying-science-infant-formula-safety; Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment on Powdered Formula for Infants and Young Children, Rome, June 15–19, 2026, *Summary and Conclusions* (July 2026), www.who.int/news-room/events/detail/2026/06/15/default-calendar/joint-fao-who-expert-meeting-on-microbiological-risk-assessment-on-microbiological-risk-assessment-on-powdered-formulae-for-infants-and-young-children.

[14] William D. Marler, Stop Foodborne Illness, et al., *Citizen Petition to Add Botulinum Neurotoxin-Producing Clostridia to the Required Microbiological Testing of Powdered Infant Formula, and to Require Testing of the Dairy-Based Ingredients from Which It Is Made* (21 C.F.R. § 10.30) (enclosed). The agency must respond within 180 days of receipt. 21 C.F.R. § 10.30(e)(2).

vote.[15] Granting the petition finishes the Senate's work. A hearing that asks the Commissioner when he will act on it is the shortest route there.

S. 272 itself was received in the House on May 4 and has been held at the Speaker's desk since. Senator Peters, who did not seek re-election, leaves the Senate in January. The bill will need a Senate sponsor in the 120th Congress if the House does not act in the weeks it has left, and so will the broader bill this body has not yet written.

The calendar

You return on Monday. Between Monday and the day the 119th Congress adjourns there are, at most, five legislative weeks, with a government funding deadline on December 11 inside them.[16] On January 3, every bill that has not been enacted dies, S. 272 and H.R. 7867 among them. There are three ways to finish this before then, and I would take any of them.

The first needs nothing from the Senate: the House passes S. 272 as it stands. It is at the Speaker's desk and needs no committee. The second: the House amends it with the testing language of H.R. 7867 and sends it back, and this Committee and the Senate pass it again the way they passed it in April. The third: the testing language rides on anything that must pass before December 11.

If none of the three happens, introduce the Senate's own bill — the companion to H.R. 7867, with the ingredient language of the enclosed petition — on the first day of the 120th Congress, with a sponsor from each party. I will write the same letter to the same Committee on January 4.

One improvement, for whichever vehicle you choose. H.R. 7867 requires testing of the facility and the finished product. The organism in these outbreaks came in on the ingredient: ByHeart has reported that all 472 of its environmental samples were negative, the FDA found no condition in ByHeart's plants that explained the contamination, and what the FDA did find was the organism in the whole milk powder.[17] A sentence adding the dairy ingredient to the testing requirement would reach the place the spores actually entered. The enclosed petition has the language.

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[15] S. 272 § 2 (new 21 U.S.C. § 350a(e)(2)) (notice required for "any microorganism for which finished product testing is required under section 106.55(e) of title 21, Code of Federal Regulations (or any successor regulation)"). The Senate-passed text mentions "events associated with botulism" only in the stakeholder reports due one, three and five years after enactment, S. 272 § 3 (new 21 U.S.C. § 350a(n)(4)). Received in the House and held at the desk, May 4, 2026. S. 272, supra note 5.

[16] Both chambers return November 9, 2026, under the published 2026 House and Senate calendars. See Roll Call, *House unveils 2026 calendar as election year nears* (Nov. 18, 2025), rollcall.com/2025/11/18/house-2026-calendar-midterm-elections/; Roll Call, *Senate releases its 2026 calendar* (Nov. 19, 2025), rollcall.com/2025/11/19/senate-calendar-2026-midterm-election/. The Continuing Appropriations and Extensions Act, 2027 (H.R. 6500), signed September 2, 2026, funds the government through December 11, 2026.

[17] Enclosed petition, Statement of Grounds, Part III, and sources cited there (ByHeart reported 472 environmental samples across its Allerton, Iowa, and Portland, Oregon, facilities, all negative; FDA's inspections identified *Clostridium botulinum* in a powdered milk ingredient, and two samples from one lot of organic whole milk powder collected at Dairy Farmers of America matched a clinical sample and a positive formula sample by whole genome sequencing); FDA, *Post-Outbreak Response Activities*, supra note 13.

What I am asking, renewed, with one addition

First, pass a bill that reaches botulism before January 3, by any of the three routes above, and introduce one on January 4 if you cannot.

Second, hold the hearing. Chairman Cassidy, your letters to ByHeart and Nara asked the right questions — what each company knew about its milk supplier, what it tested for, and when. The answers belong on a hearing record, under oath, with Dairy Farmers of America and Organic West Milk at the same table and the FDA beside them. You used the gavel to report S. 272. There is time to use it once more before January.

Third, put a written question to the FDA with a deadline. The agency has just shown that it can open Parts 106 and 107 and do the work in phases. Ask the Commissioner what the root cause investigation has found, whether botulism will be the next phase, on what schedule, and when the agency will act on the petition.

Fourth, invite the parents to testify. Fourteen of them have already written to Congress, in their own words, with their children's photographs. No expert and no lawyer, myself included, can substitute for the parent who lived it.

Fifth, and this is the addition: the families will come to you. I will fly the parents of these infants to Washington at my own expense, in the weeks you have left this year or in the first weeks of the next Congress, whichever you prefer. They will meet with any member of this Committee, in that member's office, for as long as the member has, and they will bring their children. If the Committee holds a hearing, they will testify. If it does not, they will come anyway. Give me the dates and I will book the flights.

We have done this before

The Jack in the Box rule took one decision. The 2022 formula bill took four days. This body needed one afternoon in April. The sequencing has been public for ten weeks, and fifty-two families already know what it means. Botulism does not know which party won on Tuesday. Neither did the spore that came in with the milk. You proved in April that the consensus on infant formula exists in this body. Tuesday did not repeal it.

Thank you for your leadership on S. 272, and for the chance to answer any questions from the Committee or its staff.

Very truly yours,



William D. Marler

WDM:jd
Enclosures: 1. Citizen Petition to the FDA (21 C.F.R. § 10.30), with its attachments
2. Letter to this Committee of June 29, 2026
3. Letter to this Committee of August 28, 2026

cc: The Honorable Gary Peters
The Honorable John Hoeven

1. Citizen Petition to the FDA
(21 C.F.R. Section 10.30)
With attachments.

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CITIZEN PETITION

Submitted under 21 CFR 10.30

Date: November 6, 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 Add Botulinum Neurotoxin-Producing Clostridia to the Required Microbiological Testing of Powdered Infant Formula, and to Require Testing of the Dairy-Based Ingredients from Which It Is Made

The undersigned submit this petition under sections 402, 412 and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 350a, 371(a)), 21 CFR 10.30 and 5 U.S.C. 553(e).[1]

Petitioners are William D. Marler, a lawyer who has represented victims of foodborne illness since the 1993 Jack in the Box *E. coli* O157:H7 outbreak, Stop Foodborne Illness, a national nonprofit public health organization founded after that outbreak, acting through its Chief Executive Officer, Sandra Eskin, and forty-four parents of twenty-three infants hospitalized with botulism after being fed powdered infant formula: parents of twenty-one infants sickened in the outbreak associated with ByHeart Whole Nutrition Infant Formula, and parents of two infants sickened in the outbreak associated with Nara Organics Whole Milk Organic Infant Formula. Mr. Marler and his firm represent each parent petitioner in litigation arising from these outbreaks. Nothing in this petition is offered as, or should be read as, a concession by any petitioner on any issue in that litigation.

SUMMARY

Federal regulation requires manufacturers of powdered infant formula to test finished product for two organisms, *Cronobacter* and *Salmonella*.[2] FDA added *Cronobacter* to that list in 2014 on a record of about one reported illness a year, concluding that voluntary industry testing might not be

[1] 21 U.S.C. 350a(b)(2)(A) (the Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures necessary to assure that infant formula is manufactured in a manner designed to prevent adulteration); *id.* § 350a(a)(3) (infant formula is adulterated if its processing is not in compliance with those practices and procedures); 21 U.S.C. 342(a)(1), (a)(4); 21 U.S.C. 371(a); 5 U.S.C. 553(e).

[2] 21 CFR 106.55(e) (*Cronobacter* spp., 30 samples of 10 g; *Salmonella* spp., 60 samples of 25 g; M value of 0 (none detected) for each), https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106/subpart-B/section-106.55.

enough for a food that is the sole source of nutrition for infants.[3] On March 8, 2023, the Commissioner and the Director of the Center for Food Safety and Applied Nutrition wrote to the entire powdered infant formula industry that the historical association between powdered infant formula and *Clostridium botulinum*, among other pathogens, should be considered in designing controls.[4]

Since then, 52 infants have been hospitalized with botulism in two outbreaks associated with powdered infant formula. FDA has described the first as the first botulism outbreak definitively tied to infant formula in the United States since infant botulism was first described.[5] Whole genome sequencing and a shared supply chain indicate that the two outbreaks share a common source of contamination, and the organism was found in a dairy ingredient. In June 2026, an expert group convened by the Food and Agriculture Organization of the United Nations and the World Health Organization added botulinum neurotoxin-producing clostridia to its priority hazards for powdered formula. The organism is still not on FDA's list.

This petition asks the Commissioner to finish what the agency began: add the organism to the list, and, because it arrived in a dairy ingredient, require that the ingredient be tested before it is used. Table 1 shows the change requested to the finished-product table. The other requests support those two. Each stands on its own, so that the Commissioner can grant in part what cannot be granted in whole.

Table 1. The finished-product testing table today, and as requested.

Microorganism	Number of samples / sample size	M value
Cronobacter spp. (in the rule today)	30 samples / 10 g	None detected
Salmonella spp. (in the rule today)	60 samples / 25 g	None detected
Botulinum neurotoxin-producing clostridia	Not fewer than 30 samples / not less than 200 g, or an alternative plan of equivalent or greater confidence	None detected

[3] U.S. Food & Drug Administration, *Regulatory Impact Analysis for Interim Final Rule: Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula*, Docket No. FDA-1995-N-0063, at 4–7 (2014) (*Cronobacter* identified as a pathogenic microorganism of concern in powdered infant formula; table of 21 reported U.S. illnesses associated with powdered infant formula, 1988–2009; estimate of four cases a year after adjusting for underreporting; industry's current voluntary pathogen testing and good manufacturing practice activities may not be sufficient for the sole source of nutrition for infants), https://www.fda.gov/media/89876/download. The rule is at 79 FR 7934 (Feb. 10, 2014) (interim final rule), corrected, 79 FR 9412 (Feb. 19, 2014), and 79 FR 33057 (June 10, 2014) (final rule), corrected, 79 FR 41127 (July 15, 2014).

[4] U.S. Food & Drug Administration, *Letter to the Powdered Infant Formula Industry* (Mar. 8, 2023), at 5 (signed by the Commissioner of Food and Drugs and the Director of the Center for Food Safety and Applied Nutrition), https://www.fda.gov/media/166044/download.

[5] U.S. Food & Drug Administration, Human Foods Program, *Letter to the Infant Formula Industry* (July 13, 2026) (hereinafter "July 2026 Letter"), at 1, https://www.fda.gov/media/193534/download.

The first two rows state the requirement at 21 CFR 106.55(e). The third is the amendment requested in paragraph 1 below.

A. ACTION REQUESTED

Petitioners request that the Commissioner of Food and Drugs amend 21 CFR part 106 as follows. The requests are listed in order of priority.

Definition. As used in this petition, "botulinum neurotoxin-producing clostridia" means *Clostridium botulinum* and any other *Clostridium* carrying a botulinum neurotoxin gene, including neurotoxigenic strains of *Clostridium butyricum* and *Clostridium baratii*, each a recognized cause of infant botulism.[6] A presumptive result is a positive screen by a validated method that targets the botulinum neurotoxin genes. A confirmed result is one confirmed by endopeptidase-mass spectrometry, whole genome sequencing or another confirmatory method the Commissioner specifies.

1. Add the organism to the finished-product testing table. Amend the table at 21 CFR 106.55(e) to add botulinum neurotoxin-producing clostridia, with an M value of none detected. Because contamination in these outbreaks was non-homogeneous and at very low levels, petitioners propose not fewer than thirty analytical units of not less than 200 grams each per production aggregate, the sample size used in FDA's outbreak workflow, or an alternative plan that the Commissioner determines provides equivalent or greater confidence of detection. A presumptive result should place the production aggregate on hold pending confirmation.

2. Require testing of dairy-based ingredients before they are used. Amend § 106.55 to require that, for each lot of every dairy-based ingredient that has not been subjected to a validated process capable of inactivating or reducing spores of these organisms (including whole milk powder, nonfat dry milk powder, milk protein concentrate, whey, whey protein concentrate and whey protein hydrolysate), the manufacturer test the lot, or obtain and review the supplier's results for it, by a method meeting the Definition, and that a negative result be a condition of the lot's use in infant formula. A lot with a presumptive result should be held pending confirmation. For an ingredient dried from fluid milk, testing each load of fluid milk on receipt at the drying facility, with powder made from any load with a presumptive result held pending confirmation, should satisfy this paragraph if the Commissioner determines that it provides equivalent or greater confidence of detection.

3. Require notification within one business day. Amend § 106.150 to require that a manufacturer notify FDA within one business day of any confirmed finding in a finished-product, in-process, ingredient or Zone 1 environmental sample, whether or not the affected product has left the facility.

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[6] California Department of Public Health, Infant Botulism Treatment and Prevention Program, *Laboratory Information* (*C. butyricum* and *C. baratii* produce botulinum toxin types E and F respectively, and were discovered because they caused infant botulism), https://www.cdph.ca.gov/Programs/cls/idld/ibtpp/Pages/IBTPP_Lab_Info.aspx; C.K. Fox, C.A. Keet & J.B. Strober, *Recent advances in infant botulism*, 32 Pediatric Neurology 149 (2005), https://doi.org/10.1016/j.pediatrneurol.2004.10.001.

4. Finalize the analytical method. Complete the validation of, and publish, the interim analytical workflow FDA presented on July 13, 2026, within 180 days of a decision on this petition; state that sulfite-reducing clostridia measured by direct plating is not an acceptable indicator for compliance; and, pending publication, permit any method of equivalent or greater sensitivity.

5. Require hazard identification, supplier verification and lot-level traceability. Amend § 106.6 to require a written hazard evaluation that identifies botulinum neurotoxin-producing clostridia, and other spore-forming pathogens and their toxins, including the *Bacillus cereus* toxin cereulide, as known or reasonably foreseeable hazards in dairy-based ingredients and in any other ingredient with a known association with them, such as arachidonic acid oil; a written supplier program under which the manufacturer verifies that each supplier of a dairy-based ingredient, and each facility that dries or otherwise processes it, has implemented and validated controls for those hazards, on paper and in practice; and require the manufacturer to keep, for each ingredient lot, records identifying the drying facility, the fluid milk source and each dairy farm from which that milk was obtained, available to FDA on request.

6. Require environmental monitoring as a secondary control. Amend § 106.6 to require environmental monitoring for botulinum neurotoxin-producing clostridia, at defined frequencies, in Zones 1 through 3 of any area in which the ingredients described in paragraph 2 are received, stored, handled, blended or packaged. A presumptive positive on a food-contact surface (Zone 1) should place the affected production on hold pending confirmation, and a confirmed Zone 1 positive should be reported under paragraph 3. A positive in Zone 2 or Zone 3 should trigger investigation, intensified sampling and documented corrective action.

7. In the alternative. If the Commissioner declines to grant paragraphs 1 through 6 in full, petitioners request (a) that the Commissioner grant them in part, giving priority to paragraphs 2 and 4 if the Commissioner concludes that a finished-product requirement must await a validated method; and (b) a response within the 180 days provided by 21 CFR 10.30(e)(2) and, if that response is tentative, an estimate of when a proposed rule will issue.

B. STATEMENT OF GROUNDS

I. The list, and the organism missing from it

The table at § 106.55(e) is FDA's own. The agency built it in the 2014 infant formula rulemaking because powdered infant formula is not sterile and is fed to the most vulnerable consumers there are. FDA's regulatory impact analysis for that rule shows how small a record the agency found sufficient: 21 reported U.S. *Cronobacter* illnesses associated with powdered infant formula from 1988 through 2009, about four cases a year after adjusting for underreporting.[7] FDA concluded that the industry's voluntary testing might not be enough and made the test mandatory.

The record for botulinum neurotoxin-producing clostridia is now larger. FDA named *Clostridium botulinum* to this industry in writing in March 2023. Since then, 52 infants have been hospitalized in two outbreaks, with illness onsets spanning about thirty months, across two brands, with a genomic link between them. Finished-product testing is still required for two organisms only. That

[7] See *supra* note 3.

is the whole of the argument. The rest of this statement explains why the requirement should reach the ingredient, and why it can be done now.

II. What happened

In the outbreak associated with ByHeart Whole Nutrition Infant Formula, 48 infants in 17 states became ill, with onsets from December 24, 2023, through November 29, 2025, in infants aged 16 to 264 days. All 48 were hospitalized. ByHeart recalled all its product on November 11, 2025, and CDC declared the outbreak over on February 26, 2026.[8] In the outbreak associated with Nara Organics Whole Milk Organic Infant Formula, four infants in California, Pennsylvania and Washington became ill in April and May 2026, aged 68 to 153 days. All four were hospitalized and treated with BabyBIG. Nara recalled all lots on June 13, 2026, and CDC declared that outbreak over on August 27, 2026.[9]

Table 2. The two outbreaks.

	ByHeart Whole Nutrition Infant Formula	**Nara Organics Whole Milk Organic Infant Formula**
Infants	48 (28 confirmed, 20 probable)	4 (all confirmed)
States	17	3 (California, Pennsylvania, Washington)
Illness onsets	Dec. 24, 2023, to Nov. 29, 2025	April to May 2026 (last onset May 31)
Ages at onset	16 to 264 days	68 to 153 days

[8] Reagan-Udall Foundation for the FDA, *Applying the Science of Infant Formula Safety: Insights from Recent Recall Activity and the Latest Research on C. botulinum* (Sept. 2026) (hereinafter "Roundtable Report"), https://reaganudall.org/publications/applying-science-infant-formula-safety. ByHeart and the International Dairy Foods Association funded the project. App. B, slide 3 (ByHeart summary of the CDC investigation: illness onsets Dec. 24, 2023, to Nov. 29, 2025; ages 16 to 264 days; 48 cases, 28 confirmed and 20 probable; 48 hospitalizations; 0 deaths; 17 states); FDA, *Post-Outbreak Response Activities: Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula* (content current as of Sept. 22, 2026) (hereinafter "FDA Post-Outbreak Page") (48 infants in 17 states; CDC declared the outbreak over on Feb. 26, 2026), https://www.fda.gov/food/outbreaks-foodborne-illness/post-outbreak-response-activities-clostridium-botulinum-illnesses-associated-consumption-powdered; ByHeart, Inc., *ByHeart Updates Information Regarding Voluntary Recall of All Batches of ByHeart Whole Nutrition Infant Formula Cans and Packs Because of Possible Health Risk* (posted by FDA Nov. 11, 2025; updated Nov. 19, 2025) (recall includes all batch codes and use-by dates), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/byheart-broadens-voluntary-recall-while-investigation-continues.

[9] Centers for Disease Control and Prevention, *Investigation Update on Infant Botulism Outbreak, June 2026* (updates of July 6 and Aug. 27, 2026) (four confirmed cases in California (2), Pennsylvania (1) and Washington (1); all hospitalized and treated with BabyBIG; ages 68 to 153 days at onset; outbreak over), https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-june-2026/investigation.html; U.S. Food & Drug Administration, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)* (update of Aug. 27, 2026) (hereinafter "FDA Nara Advisory") (recall of all lots June 13, 2026; last illness onset May 31, 2026), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-powdered-infant-formula-june-2026.

	ByHeart Whole Nutrition Infant Formula	**Nara Organics Whole Milk Organic Infant Formula**
Hospitalized	48 of 48	4 of 4
Recall	All product, Nov. 11, 2025	All product, June 13, 2026
Outbreak declared over	Feb. 26, 2026	Aug. 27, 2026

Sources: CDC and FDA outbreak pages for both outbreaks; ByHeart's summary of the CDC investigation, Roundtable Report, App. B, slide 3.

On August 27, 2026, FDA reported that a clinical sample from the Nara outbreak matched, by whole genome sequencing, a clinical sample from the ByHeart outbreak, a ByHeart base powder sample and four unopened cans of ByHeart formula. Formula from both brands was made with milk supplied by Organic West Milk and spray dried by Dairy Farmers of America. FDA concluded that the matches and the shared supply chain indicate a common source of contamination, and that it does not yet have enough evidence to say whether the milk was contaminated before or during drying.[10] Where in the milk stream contamination began matters for root cause and for apportioning responsibility. It does not change whether anyone should be required to look for the organism.

III. The organism came in with the ingredient, so the control belongs there

ByHeart reported 472 environmental samples across its Allerton, Iowa, and Portland, Oregon, facilities, covering Zones 1 through 4 and HVAC pre-filters. All were negative.[11] FDA's inspections identified the organism in a powdered milk ingredient, and two samples from one lot of organic whole milk powder collected at Dairy Farmers of America matched a clinical sample and a positive formula sample by whole genome sequencing.[12] A control aimed at the plant environment would have found nothing. The cereulide recalls of 2025 and 2026, summarized at Appendix C, followed the same pattern with a different spore-former and a different ingredient.

[10] FDA Nara Advisory (update of Aug. 27, 2026) (one clinical sample from the Nara outbreak matched a clinical sample from the 2025 ByHeart outbreak, a powdered infant formula base sample and four samples of unopened cans of ByHeart formula; formula lots from both brands made with milk supplied by Organic West Milk and spray dried by Dairy Farmers of America; matching results and supply-chain commonalities indicate a common source; not enough evidence to determine whether the milk was contaminated before or during drying); CDC, *Investigation Update*, supra (whole genome sequencing linked the Nara patient sample to a patient sample, product samples and an ingredient sample from the 2025 investigation).

[11] Roundtable Report, App. B, slides 6 and 9. The data are reproduced at Appendix A. Slide 9 reports environmental results for ByHeart's Allerton, Iowa, and Portland, Oregon, facilities and none for its Reading, Pennsylvania, bulk-powder facility; petitioners draw no conclusion about the Reading environment.

[12] FDA Post-Outbreak Page (FDA inspections of ByHeart's facilities identified *Clostridium botulinum* in a powdered milk ingredient; two samples from one lot of organic whole milk powder collected at Dairy Farmers of America matched a clinical sample and a positive infant formula sample by whole genome sequencing); July 2026 Letter at 1.

Paragraphs 2 and 5 of the Action Requested therefore put the primary control on the ingredient and its sources, and paragraph 6 treats environmental monitoring as secondary.

FDA's own first look at powdered milk supply points the same way. In February 2026 the agency collected 48 powdered milk samples from four suppliers to infant formula manufacturers. Two samples of organic nonfat milk powder from one firm were PCR-positive, and whole genome sequencing identified *Clostridium sporogenes* carrying a gene highly associated with botulinum toxin B1, which FDA said suggests, but does not confirm, an ability to produce toxin. That powder was not used in infant formula.[13] This finding is also why the Definition reaches the toxin gene rather than a single species name. Neurotoxigenic *C. butyricum* and *C. baratii* are recognized causes of infant botulism, and a rule written for *C. botulinum* by name could miss them.[14]

The spore source is the dairy system itself. Research presented to FDA at the July 2026 roundtable traced spores from soil and feed through bedding and manure to bulk tank milk and described spore-reduction technologies as meaningful but incomplete.[15] A hazard that lives on the farm will be managed, not eliminated, and a supplier's records are the only way to know which farm a lot came from. During the 2025 investigation, Organic West Milk gave FDA an incomplete customer list that omitted Nara's manufacturers; the first Nara infant became ill about five months after the ByHeart recall.[16] Reporters have since found that FDA traced the milk to 22 dairies that have not been publicly identified and ByHeart has said it had no visibility into the farms its supplier used.[17] Paragraph 5 puts that record in the manufacturer's files.

The international scientific advice now points the same way. In June 2026, at the request of the Codex Committee on Food Hygiene, the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment reviewed the evidence on powdered formula and added botulinum neurotoxin-producing clostridia, together with the *Bacillus cereus* toxin cereulide, to the priority group of hazards that already included *Salmonella* and *Cronobacter*, the two organisms on FDA's list. The expert group found that dairy ingredients have been demonstrated as a vehicle for these spores, that their control starts with on-farm practices, that powdered formula production processes are not designed to eliminate them, and that manufacturers should implement supplier risk

[13] FDA Post-Outbreak Page (February 2026 initial surveillance sampling assignment: 48 powdered milk samples from four suppliers to infant formula manufacturers, 12 per supplier; 46 negative by PCR; two organic nonfat milk powder samples from the same firm PCR-positive; whole genome sequencing confirmed *Clostridium sporogenes* with a gene highly associated with botulinum toxin B1, which "suggests – but does not confirm" that the bacterium could produce botulinum toxin; the powdered milk was not used to manufacture infant formula).

[14] See *supra* note 6.

[15] Roundtable Report, App. C (Nicole Martin, PhD, Cornell University, "Bacterial spore prevalence in the dairy system and mitigation strategies"), slides 3, 5, 8, 11, 15, 17 and 19.

[16] FDA Nara Advisory (update of June 26, 2026) (during the 2025 investigation, Organic West Milk provided an incomplete customer list that did not indicate it supplied milk to manufacturers of Nara Organics formula, and later informed FDA that the list should have included them).

[17] Lisa Fletcher, Andrea Nejman, Young Richardson & Nathan Aaron, *No answers about cause of botulism in baby formula; experts fear another outbreak*, WJLA 7News I-Team / Spotlight on America (Oct. 8, 2026) (internal FDA documents show the milk was traced to 22 dairies, none publicly identified; no evidence found that FDA sent investigators to the farms; ByHeart statement that it had no visibility or control over the specific farms chosen by its supplier; Nara did not answer questions about its milk source), https://wjla.com/features/i-team/no-answers-about-the-cause-of-botulism-in-baby-formula-experts-fear-another-outbreak-bill-marler-food-safety-network.

management programs addressing them in ingredients.[18] It framed the hazard as this petition's Definition does, by the toxin rather than by a single species name.

IV. The method and the capacity exist

Testing at commercial scale has already been done. ByHeart reported about 5,000 *C. botulinum* tests run by IEH Laboratories during its root-cause investigation, including 2,348 tests on fifteen lots of whole milk powder; IEH reported nine positives among 4,675 samples.[19] ByHeart described routine testing of all dairy ingredients, bulk powder and finished product, with results required as a release criterion.[20] ByHeart has since been discontinued and will not relaunch, so that commitment will never be tested, and a company led by ByHeart's co-founders has agreed to acquire Perrigo's store-brand infant formula business.[21] Nothing requires that business, or any other manufacturer, to test for this organism.

FDA has written the method. At the July 13, 2026, roundtable, the agency presented an interim workflow using a 200-gram sample, enrichment, qPCR, endopeptidase-mass spectrometry, whole genome sequencing and mouse bioassay, captioned as pending validation and approval.[22] Validation and approval are steps the agency controls, which is why paragraph 4 asks for a schedule. The rule should also say which methods do not count: ByHeart's investigation showed that spores can be present at levels too low for detection of sulfite-reducing clostridia by direct plating, yet high enough to make infants sick.[23] Even the roundtable report funded by ByHeart and the International Dairy Foods Association recommends that FDA establish standardized testing methods and requirements.[24]

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[18] Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment on Powdered Formula for Infants and Young Children, FAO HQ, Rome, Italy, June 15–19, 2026, *Summary and Conclusions* (issued July 2026) (hereinafter "JEMRA Summary"), at 2–4 (priority group updated to include BoNT-producing clostridia and *Bacillus cereus* s.l. (cereulide); dairy ingredients have been demonstrated as a vehicle for BoNT-producing clostridial spores resulting in contamination of powdered formula; control starts with on-farm practices; production processes are not designed to eliminate the spores; manufacturers should implement supplier risk management programs addressing BoNT-producing clostridia and cereulide in ingredients), https://cdn.who.int/media/docs/default-source/food-safety/jemra/jemra-pf_final.pdf.

[19] Roundtable Report, App. B, slides 8, 9 and 13 (approximately 5,000 *C. botulinum* tests by IEH Laboratories; over 1,000 isolates screened; IEH reported nine positives out of 4,675 samples). See Appendix A.

[20] Roundtable Report, App. B, slides 15 and 16 (ByHeart response to FDA describing routine sampling and validated methods for *C. botulinum* across all dairy ingredients, bulk powder and finished products, with results required as a release criterion).

[21] Anna Edney, Bloomberg News (Oct. 29, 2026) (MeridianMade, led by ByHeart co-founders, agreed to acquire Perrigo's infant formula business for up to $175 million, with closing expected in the first half of 2027; a MeridianMade spokesperson stated that ByHeart has been discontinued and will not relaunch).

[22] Roundtable Report, App. D (FDA, "Summary *C. Botulinum* Workflow (outbreak)": 200 g sample; enrichment under Bacteriological Analytical Manual Chapter 17; qPCR; endopeptidase-mass spectrometry; isolation; whole genome sequencing; mouse bioassay; captioned "Interim Workflow, finalization pending method validation and approval").

[23] Roundtable Report at 9; *id.* App. B, slide 11; C. Nadala *et al.*, *Detection and characterization of Clostridium botulinum isolated from powdered infant formula*, 17 Frontiers in Microbiology 1800624 (2026), https://doi.org/10.3389/fmicb.2026.1800624.

[24] Roundtable Report, App. A Recommendation 17.

The same expert group recorded the strongest practical objection to this petition, and petitioners include it here: spores in contaminated powdered formula have been found at concentrations below one per 100 grams, and detecting them requires costly resources, laboratory authorizations and specialized skills.[25] That is why paragraph 1 specifies large analytical units, and why paragraph 4 asks the agency to finish validating one method rather than leave each manufacturer to choose its own. It is also a reason to test upstream. A food microbiologist who commented on the draft of this petition observed that a low-level contaminant is more evenly mixed in fluid milk at the drying facility's gate than in finished powder and has not yet been divided among lots. Paragraph 2 therefore allows testing of each load of fluid milk on receipt as an alternative, if it provides equivalent or greater confidence of detection.

V. Anticipated objections

Prevalence data should come first. The roundtable report recommends an initial assessment of prevalence on farms, in the supply chain and in finished goods.[26] Petitioners support that work. But testing is how prevalence data is generated; FDA's own 48-sample assignment is an example. Deferring a requirement until the data exist leaves the interval uncovered, and the last uncovered interval in this product category, the ByHeart outbreak, ran nearly twenty-three months from first illness onset to recall.

Testing will threaten supply. The 2022 shortage was driven largely by contamination at a single plant and the shutdown that followed, not by the testing that found it.[27] Catching contamination in an ingredient lot, before it is blended into a production aggregate, is how recalls and shutdowns are avoided.

Existing rules already cover suppliers. Parts 106 and 117 require ingredient specifications, audits, a hazard analysis and, where a firm identifies a supply-chain-applied control, supplier verification.[28] Each turns on what the manufacturer decides is a hazard requiring a control. Until November 2025 the industry relied on an international recommendation that routine testing for *C. botulinum* in powdered infant formula was not warranted.[29] FDA has since asked the International Commission on Microbiological Specifications for Foods to revisit that recommendation and has

[25] JEMRA Summary at 3 (low concentrations of BoNT-producing clostridial spores found in contaminated powdered formula (<1 per 100 g) present challenges in detection and enumeration requiring costly resources, laboratory authorizations and specialized skills; indicators of the spores should be evaluated for their feasibility and accuracy).

[26] Roundtable Report, App. A Recommendations 1 and 5.

[27] National Advisory Committee on Microbiological Criteria for Foods, *Cronobacter spp. in Powdered Infant Formula* (FDA charge to the 2022 subcommittee) (the resulting recall and temporary plant shutdown were a major contributing factor to the 2022 infant formula shortage), https://www.fsis.usda.gov/node/5137.

[28] July 2026 Letter at 2–3 (21 CFR part 106 requires ingredient specifications, quarantine and disposition of nonconforming ingredients, and regularly scheduled audits; 21 CFR part 117 requires a hazard analysis, preventive controls and, if applicable, a supply-chain program with supplier verification).

[29] Roundtable Report, App. B, slide 4 (reproducing an International Commission on Microbiological Specifications for Foods recommendation against routine testing for *C. botulinum* in powdered infant formula); *id.* at 5.

supported a Codex request for expert advice on this organism in powdered infant formula.[30] A requirement in § 106.55 takes the decision away from the individual firm and gives it to the agency.

Testing cannot make food safe. Petitioners agree that no one can test a way to food safety, and that a negative result shows only that the organism was not found in the units analyzed. The Food Safety Modernization Act rests on that premise, and preventive controls are the first line of defense. This petition does not ask the Commissioner to choose between them. Paragraph 5 asks that every manufacturer name the hazard in its hazard evaluation and verify that its suppliers control it; the testing in paragraphs 1 and 2 verifies that those controls work, the role finished-product testing for *Cronobacter* and *Salmonella* already plays in part 106. Verification matters most for a hazard like this one. Spores come from the farm, survive drying and preparation with hot water, are spread unevenly through a lot, and can be present at levels below what direct plating detects yet high enough to make infants sick. FDA told the industry in March 2023 to consider this organism in designing controls. The first infant in the ByHeart outbreak became ill nine months later, and illnesses continued for nearly two years before a recall. Advice to plan for a hazard, without a requirement to verify that the plan works, is what this record shows to be insufficient. Nor should the prospect of a false positive deter the requirement. The Definition separates a presumptive result from a confirmed one, a presumptive result places product on hold rather than condemning it, and only a confirmed result triggers notification under paragraph 3. Petitioners also agree that the causes of these outbreaks should be published so that every processor can address them. As sections II and III describe, that has not happened: FDA has not said whether the milk was contaminated before or during drying, and the dairies to which the milk was traced have not been identified.

VI. The Commissioner has the authority

Section 412 of the Act directs FDA to establish by regulation good manufacturing practices, including quality control procedures, designed to prevent adulteration of infant formula, and deems formula adulterated if it is not processed in compliance with them.[31] The statute specifically contemplates in-process controls including testing, and the retention of records on the microbiological quality of raw materials, available to the agency on request.[32] Paragraphs 1, 2 and 5 of the Action Requested ask for exactly those things. No new authority is needed: § 106.55 is the agency's rule, and the table at § 106.55(e) is the agency's list. The agency also has the infant formula regulations open now. On October 29, 2026, FDA issued the first of three planned proposed rules revising the infant formula nutrient requirements, its first comprehensive review of those requirements since 1998, and said it intends to consolidate the changes in a single final rule.[33]

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[30] July 2026 Letter at 3 (FDA supported the Codex Committee on Food Hygiene's request for scientific advice from the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment on *Clostridium botulinum* and *Bacillus cereus* in powdered infant formula and requested that ICMSF consider revisiting its publication on the usefulness of testing for *C. botulinum* in powdered infant formula and dairy-based ingredients); FDA Post-Outbreak Page.

[31] See *supra* note 1.

[32] 21 U.S.C. 350a(b)(2)(B)(iii) (in-process controls including, where necessary, testing designed to prevent adulteration of each batch); *id.* § 350a(b)(4)(A)(iv)(I) (retention of all records pertaining to the microbiological quality and purity of raw materials used in infant formula powder); *id.* § 350a(b)(4)(B)(i) (records to be made available to the Secretary on request).

[33] U.S. Department of Health & Human Services, *Trump Administration Announces First Major Update to Infant Formula Standards in Nearly 30 Years* (Oct. 29, 2026) (first of three planned proposed rules;

The agency has shown that it can amend the infant formula regulations in phases. The requests in this petition can be the next phase. The testing data FDA released the same day concerned chemical contaminants, not pathogens.

The list also matters to Congress. The Senate passed S. 272 by unanimous consent in April 2026. Its one-business-day notice duty applies to any microorganism for which finished-product testing is required under § 106.55(e), and the bill separately directs FDA to consult on testing for contamination events, including those associated with botulism.[34] If the bill is enacted, adding this organism to the list extends that notice duty to it without further legislation. If the House does not act before the 119th Congress adjourns, the bill lapses; the Commissioner's authority does not. The legislative record is summarized at Appendix B.

VII. The population

Powdered infant formula is fed as the sole source of nutrition to people who cannot be warned. The infants in these two outbreaks were between 16 and 264 days old. There is no rinse step and no cooking step, and preparing formula with hot water does not destroy botulinum spores; the FAO/WHO expert group has concluded that preparation advice designed for *Salmonella* and *Cronobacter* may not be effective against them[35]; whatever is in the can goes into the child. BabyBIG, the only licensed antitoxin for infant botulism, carries a per-patient fee of $69,300 set by California regulation, and all four Nara infants received it.[36] If each of the fifty-two infants were treated, that is $3,603,600 in antitoxin alone, before intensive care, ventilation, feeding tubes, rehabilitation, recalls or plant shutdowns.

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first comprehensive review of infant formula nutrients since 1998; FDA intends to consolidate final changes into a single comprehensive final rule; release of chemical contaminant testing data), https://www.hhs.gov/press-room/fda-updates-infant-formula-standards-first-time-30-years.html; FDA, *Infant Formula Nutrient Requirements*, proposed rule, Docket No. FDA-2026-N-10832, RIN 0910-AJ34, FR Doc. 2026-22273 (Fed. Reg. publication Nov. 2, 2026).

[34] *Protect Infant Formula from Contamination Act*, S. 272, 119th Cong. §§ 2–3 (as passed by the Senate) (§ 2: one-business-day notice of a confirmed positive result for any microorganism for which finished product testing is required under 21 CFR 106.55(e) or any successor regulation; § 3: stakeholder engagement on evidence-based practices, which may include high frequency testing for identifying contamination events, including events associated with botulism), https://www.congress.gov/bill/119th-congress/senate-bill/272 (passed Senate by unanimous consent Apr. 28, 2026; held at the desk in the House May 4, 2026); Congressional Budget Office, *S. 272* (cost estimate) (bill would impose responsibilities for contamination involving *Cronobacter* or *Salmonella*), https://www.cbo.gov/publication/62204. See Appendix B.

[35] JEMRA Summary at 4 (current consumer preparation recommendations designed to reduce the risk posed by *Salmonella* and *Cronobacter* spp. may not be effective for the control of BoNT-producing clostridial spores).

[36] Cal. Code Regs. tit. 17, § 3030 (per-patient fee for Botulism Immune Globulin of $69,300, effective July 1, 2025), as amended by California Department of Public Health, DPH-25-005, *Postponement of BabyBIG® Fee Increase* (Apr. 9, 2025), https://www.cdph.ca.gov/Programs/OLS/CDPH%20Document%20Library/DPH-25-005-BabyBIG_Fee_FP.pdf; CDC, *Investigation Update*, supra (all four Nara Organics infants treated with BabyBIG).

In 2014, on a record of about one reported case a year, FDA decided that testing for *Cronobacter* should not be left to voluntary practice. The record for this organism is now larger, and the agency has already named it. Petitioners respectfully ask the Commissioner to add it to the list.

C. ENVIRONMENTAL IMPACT

Petitioners claim a categorical exclusion under 21 CFR 25.30(j), which covers the issuance of current good manufacturing practice regulations. The action requested amends a current good manufacturing practice regulation, 21 CFR part 106, to add testing, monitoring, recordkeeping and notification requirements to a manufacturing process already subject to regulation. To petitioners' knowledge, no extraordinary circumstances exist. If the Commissioner determines that no categorical exclusion applies, petitioners will furnish an environmental assessment on request.

D. ECONOMIC IMPACT

Information on the economic impact of the requested action will be submitted upon request of the Commissioner in accordance with 21 CFR 10.30(b). The record supplies a direct basis for that analysis: one manufacturer has performed and publicly reported testing at the scale this petition would require, and the per-patient fee for the only available treatment is set by California regulation.

E. CERTIFICATION

The undersigned certify 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 petitioners which are unfavorable to the petition.

Respectfully submitted,



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/s/ Anthony Mazziotti
Anthony Mazziotti

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Erica Nelson

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/s/ Aman Chughtai
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/s/ Tooba Chughtai
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/s/ Derek Connolly
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/s/ Kieley Weaver
Kieley Weaver

/s/ Cole Weaver
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Tyler Wescott

/s/ Madi Wescott
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/s/ Jin Nam
Jin Nam

/s/ Jisun Lee
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/s/ Erica Goldfin
Erica Goldfin

/s/ Micky Goldfin
Micky Goldfin
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cc: The Honorable Secretary of Health and Human Services
Commissioner of Food and Drugs, U.S. Food and Drug Administration
Director, Office of Critical Foods, Human Foods Program, U.S. Food and Drug Administration
Deputy Commissioner for Food, Human Foods Program, U.S. Food and Drug Administration
Chief Counsel, U.S. Food and Drug Administration
The Honorable Brett Guthrie, Chairman, and The Honorable Frank Pallone, Jr., Ranking Member, Committee on Energy and Commerce, U.S. House of Representatives
The Honorable Bill Cassidy, M.D., Chairman, and The Honorable Bernie Sanders, Ranking Member, Committee on Health, Education, Labor, and Pensions, United States Senate

APPENDIX A
ByHeart testing data reported to the July 13, 2026, roundtable

The two tables below reproduce data ByHeart presented at the roundtable FDA attended (Roundtable Report, App. B, slide 9). They are included because they show where the organism was and was not found, including data unfavorable to the environmental-monitoring request in paragraph 6.

Table A-1. Environmental testing, by zone: 472 samples, no positives.

Zone	Allerton, IA	Portland, OR	Positives
Zone 1	244	26	0
Zone 2	100	26	0
Zone 3	49	12	0
Zone 4	3	2	0
HVAC pre-filters	10	0	0
Total	**406**	**66**	**0**

The slide reports no environmental results for ByHeart's Reading, Pennsylvania, bulk-powder facility.

Table A-2. Ingredient, bulk base and finished-product testing.

Sample type	Lots	Individual tests	Lots PCR positive	Lots culture confirmed
GOS	5	5	0	—
Lactoferrin	37	30	0	—
Lactose	47	552	0	—
Whole milk powder	15	2,348	1	1
Whey protein concentrate	23	257	0	—
Whey protein hydrolysate	22	458	1	0
Other ingredients	65	108	0	—
ByHeart bulk base	22	83	3	1
ByHeart finished product	241	387	8	6

The slide states that the one confirmed positive ingredient was whole milk powder. This table counts lots; other figures in the record count individual samples, which is why they differ.

APPENDIX B
The response to date, and the legislative record

Table B-1. Federal and related actions, March 2023 to October 2026.

Date	Action	Binding on anyone?
Mar. 8, 2023	Letter to the powdered infant formula industry, signed by the Commissioner and the Director of CFSAN, naming *Clostridium botulinum*	No. A letter.
Mar. 18, 2025	Operation Stork Speed announced, including increased testing for heavy metals and other contaminants in infant formula and other foods children consume	No. An initiative.
Feb. 2026	Initial surveillance sampling: 48 powdered milk samples from four suppliers; two positives for *C. sporogenes* carrying a BoNT/B1 gene	No. Agency sampling.
2025–2026	FDA advocates a JEMRA risk assessment of spore-formers in powdered infant formula and supports a Codex request for scientific advice	No. A referral.
May 13, 2026	Human Foods Program announces a collaborative vision for enhancing food safety	No. An announcement.
July 13, 2026	Letter to industry on ingredient selection, ingredient sources and supply-chain oversight; FDA asks ICMSF to revisit its testing publication	No. A letter.
July 13 / Sept. 2026	Invitation-only Reagan-Udall Foundation roundtable, attended by FDA, convened with ByHeart and IDFA, which funded it; report with twenty-two recommendations	No. A report.
June–July 2026	FAO/WHO expert meeting (JEMRA) of June 15–19, 2026, summary issued July 2026, convened at the Codex request FDA supported, adds BoNT-producing clostridia to the priority hazards for powdered formula and finds dairy ingredients a demonstrated vehicle	No. Scientific advice.
Oct. 29, 2026	FDA issues the first of three proposed rules on infant formula nutrient requirements and releases chemical contaminant testing data	No. A proposed rule, and it does not address pathogens.
Today	21 CFR 106.55(e) requires finished-product testing for *Cronobacter* and *Salmonella* only	Yes, and it does not reach this organism.

Sources: FDA Post-Outbreak Page; July 2026 Letter; HHS and FDA, Operation Stork Speed announcement (Mar. 18, 2025); FDA, HFP Advances Collaborative Vision for Enhancing Food

Safety (May 13, 2026); Roundtable Report; JEMRA Summary; HHS, Trump Administration Announces First Major Update to Infant Formula Standards in Nearly 30 Years (Oct. 29, 2026).

S. 272, the Protect Infant Formula from Contamination Act

The Senate passed S. 272 by unanimous consent on April 28, 2026, after the Committee on Health, Education, Labor, and Pensions reported it 22 to 0. It was received in the House and held at the desk on May 4, 2026. Section 2 requires one-business-day notice of a confirmed positive result "for any microorganism for which finished product testing is required under section 106.55(e) of title 21, Code of Federal Regulations (or any successor regulation)," regardless of whether the product has left the manufacturer's control. The sponsors' section-by-section summary and the Congressional Budget Office describe the bill as reaching *Cronobacter* and *Salmonella*, because those are the two organisms on the list today. Section 3, as passed, directs FDA to engage stakeholders on evidence-based practices, which may include high-frequency testing for contamination events, including events associated with botulism.

H.R. 7867, the Infant Formula Safety Modernization Act of 2026

Introduced March 9, 2026, by Rep. Rosa DeLauro, with bipartisan cosponsors, now more than forty, including Rep. Jeff Van Drew, and referred to the Committee on Energy and Commerce. The bill was among the bills considered at a Subcommittee on Health legislative hearing on April 29, 2026, and has not been marked up. The bill would direct FDA to establish a list of pathogens for which infant formula must be tested, including *Clostridium botulinum*, and would require environmental monitoring. Petitioner Marler wrote in support to the Committee on Energy and Commerce on June 23 and August 28, 2026, and to the Senate Committee on Health, Education, Labor, and Pensions on June 29 and August 28, 2026. Those letters are reproduced at Attachment 1.

APPENDIX C
A parallel ingredient failure

From December 2025 to February 2026, infant formula from Nestlé, Danone and others was recalled in multiple countries after cereulide, a heat-stable toxin of the spore-forming bacterium *Bacillus cereus*, was traced to arachidonic acid (ARA) oil from a single third-party supplier. FDA reports nearly 150 suspected and confirmed cases across ten countries. On May 2, 2026, the a2 Milk Company recalled imported infant formula from the U.S. market because of cereulide, and on May 12, 2026, the supplier's ARA oil products were placed on FDA Import Alert 99-51. The U.K. Health Security Agency had received 36 clinical notifications by February 3, 2026. The pattern is the one documented here: one ingredient, several brands, many markets. (Sources: July 2026 Letter at 2; U.K. Health Security Agency, Health Protection Report vol. 20, issue 1 (Jan. 29 and Feb. 5, 2026); Food Safety Authority of Ireland and U.K. Food Standards Agency recall notices, January and February 2026.)

APPENDIX D
Sources cited

Statutes and regulations

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Letter to the Infant Formula Industry (July 13, 2026), https://www.fda.gov/media/193534/download.

ByHeart Updates Information Regarding Voluntary Recall of All Batches of ByHeart Whole Nutrition Infant Formula Cans and Packs Because of Possible Health Risk (FDA posting Nov. 11, 2025), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/byheart-broadens-voluntary-recall-while-investigation-continues.

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Outbreak Investigation of Infant Botulism: Infant Formula (November 2025).

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HHS, FDA Announce Operation Stork Speed to Expand Options for Safe, Reliable, and Nutritious Infant Formula for American Families (Mar. 18, 2025).

HFP Advances Collaborative Vision for Enhancing Food Safety (May 13, 2026).

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CDC, Investigation Update: Infant Botulism Outbreak (November 2025 outbreak).

California Department of Public Health, IBTPP, Laboratory Information; DPH-25-005, Postponement of BabyBIG® Fee Increase (Apr. 9, 2025).

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C.K. Fox, C.A. Keet & J.B. Strober, Recent advances in infant botulism, 32 Pediatric Neurology 149 (2005).

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H.R. 7867, 119th Cong. (2026).

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ATTACHMENT 1
Correspondence with the Committees of Jurisdiction, June–August 2026

Letter to the Committee on Energy and Commerce, U.S. House of Representatives, June 23, 2026, in support of H.R. 7867, with statements and photographs of fourteen families. https://www.marlerblog.com/files/2026/08/HR_7867_Support_Letter_6_23_26_WDM_FINAL.pdf

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Follow-up letter to the Committee on Energy and Commerce, August 28, 2026. https://www.marlerblog.com/files/2026/08/HR7867_Follow_Up_Letter_8-28-26.pdf

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2. Letter to this Committee of June 29, 2026

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June 29, 2026

The Honorable Bill Cassidy, M.D., Chairman
The Honorable Bernie Sanders, Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC 20510

Re: Finish what the Senate started — botulism in infant formula, the shared milk and powdered-milk supply behind two outbreaks, and the case for hearings and parent testimony

Dear Chairman Cassidy, Ranking Member Sanders, and Members of the Committee:

For more than thirty years — since the 1993 Jack in the Box *E. coli* outbreak — I have represented children and families poisoned by food they trusted. I now represent the families of more than twenty-five infants paralyzed by botulism in the first months of their lives because of contaminated powdered infant formula. I wrote to this Committee's House counterpart last week in support of H.R. 7867, the Infant Formula Safety Modernization Act of 2026[1], and I am writing to you now because the Senate has already shown what this body can do on this issue — and because the work is not finished.

You have already led on this — and it mattered

Let me begin with credit, because you have earned it. On April 29, 2026, this Committee reported the Protect Infant Formula from Contamination Act, S. 272, favorably by a vote of 22 to 0, and the full Senate passed it the same day by unanimous consent.[2] Bipartisan legislation, introduced by Senators Gary Peters and John Hoeven, cleared this body without a single dissenting voice. That is not a small thing. In a Washington that agrees on almost nothing, the Senate agreed that parents

[1] William D. Marler, *Support for H.R. 7867, the Infant Formula Safety Modernization Act of 2026* (June 23, 2026) (letter to the House Committee on Energy and Commerce, with Appendix A — statements and photographs of affected ByHeart and Nara families), Marler Blog, marlerblog.com; full letter (PDF), HR_7867_Support_Letter_6_23_26_WDM_FINAL.pdf.

[2] Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), congress.gov/bill/119th-congress/senate-bill/272. Reported favorably by the Senate HELP Committee 22–0 and passed by the full Senate by unanimous consent on April 29, 2026. See Press Release, Sen. Gary Peters, *Senate Passes Peters' Bipartisan Legislation to Prevent Infant Formula Shortages* (Apr. 29, 2026), peters.senate.gov.

deserve to be told, within one business day, when the formula in their baby's bottle has tested positive for a deadly pathogen.

That achievement fits squarely within the food-safety agenda th Administration has championed under the banner of Making America Healthy Again. The MAHA movement has put the safety and integrity of what we feed our children at the center of the national conversation — Operation Stork Speed forced the first serious look at infant formula in a generation, and the FDA's April 2026 contaminant testing was the largest this country has ever conducted.[3] I have said publicly, and I will say it to you, that this work is long overdue and I am glad it is happening. The Senate's passage of S. 272 is of a piece with it. You closed a real gap, and you should be proud of it.

But S. 272 does not reach the pathogen that actually paralyzed these babies

Here is the hard part, and I say it as someone who supports what you did. S. 272 requires one-business-day notice only for the organisms already on the books — *Cronobacter* and *Salmonella*. It does not reach *Clostridium botulinum*, the spore-forming organism that produced the toxin that hospitalized 48 infants across 17 states in the ByHeart outbreak[4] and three more infants in California, Pennsylvania, and Washington in the Nara Organics outbreak.[5] Every one of those 51 babies was hospitalized. Many were placed on ventilators. Each was treated with BabyBIG antitoxin, which the State of California prices at $69,300 per dose.[6] Not one of them was harmed by the contaminants the April testing screened for. They were paralyzed by a spore that no federal regulation requires anyone to test powdered formula for, before or after it ships.

The hazard was not a surprise. On March 8, 2023 — two years before the first ByHeart baby fell ill — the FDA sent a Call-to-Action letter to the entire powdered infant formula industry, signed by the Commissioner of Food and Drugs and the Director of the Center for Food Safety and Applied Nutrition, naming *Clostridium botulinum* by genus and species and instructing manufacturers to account for it in the design of their controls.[7] The danger was foreseeable, it was named in writing by the government, and the rule still does not require the test. H.R. 7867 — led by Representative Rosa DeLauro and Representative Jeff Van Drew, and endorsed by the American Academy of Pediatrics, Consumer Reports, the Consumer Federation of America, the Center for Science in the Public Interest, STOP Foodborne Illness, and others — is the bill that names *botulism* on the testing list, mandates environmental monitoring inside the plant, and holds

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[3] FDA, *FDA Releases Results from Largest-Ever Testing of Infant Formula in the U.S.* (Apr. 29, 2026), fda.gov; see also FDA, *Operation Stork Speed*, fda.gov/food/infant-formula-homepage/operation-stork-speed.
[4] FDA, *Outbreak Investigation of Infant Botulism: Infant Formula (November 2025)* (ByHeart; 48 infants in 17 states, all hospitalized; whole-genome sequencing linking the organism across a clinical isolate, finished formula, and incoming organic whole milk powder dried at Dairy Farmers of America), fda.gov.
[5] FDA, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)* (Nara Organics; three infants in California, Pennsylvania, and Washington, ages two to five months, treated with BabyBIG), fda.gov.
[6] California Dep't of Public Health, Infant Botulism Treatment & Prevention Program, BabyBIG® Fee Schedule — $69,300 per dose (eff. July 1, 2025), cdph.ca.gov.
[7] FDA, *FDA's Actions to Respond to Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula* (discussing the March 8, 2023 Call-to-Action letter to the powdered infant formula industry, signed by the Commissioner of Food and Drugs and the Director of CFSAN, naming *Clostridium botulinum*), fda.gov; letter text at fda.gov/media/166044/download.

foreign manufacturers to American standards.[8] The Senate did the narrower bill. The House has the broader one in front of it now.

My first ask is simple: I asked the House to move on H.R. 7867. I am asking the Senate to do the same. *Take up companion legislation, or your own measure, that closes the botulinum gap S. 272 left open — and finish what this Committee started on April 29.*

Why the system missed it twice — and why this Committee should hold hearings

The two outbreaks were not unrelated coincidences. They shared a supply chain. The FDA's own traceback has now confirmed that the Nara formula fed to the three sick infants was made with milk supplied by Organic West Milk and spray-dried by Dairy Farmers of America — the same two suppliers linked to the ByHeart outbreak.[9] One upstream source furnished the milk and the powdered milk behind both brands. The contamination did not strike two companies by chance; it traveled through one shared stream that the system missed the first time and then missed again.

During the 2025 ByHeart investigation, the FDA did exactly what the playbook calls for: it ran a trace-forward and asked Organic West who else it supplied, so the next brand could be found before the next baby got sick. According to the FDA's June 26, 2026 update, the customer list Organic West produced was incomplete — it did not include Nara — and Organic West has now admitted the list should have listed Nara. The trace-forward happened during the 2025 outbreak. The Nara babies were hospitalized in April and May 2026. A complete, accurate list could have put Nara on the FDA's radar months before a single infant showed a symptom. The one mechanism designed to prevent the second outbreak existed, the agency used it, and an incomplete supplier disclosure defeated it.

That is precisely the kind of failure congressional oversight exists to examine. The questions are concrete, and the answers belong on the record, under oath:

1. **Questions to the FDA:** When did the agency learn that Organic West and DFA supplied both ByHeart and Nara? Why did the 2025 trace-forward fail to surface Nara, what is the backstop when a supplier's customer list is incomplete, and why does federal regulation still require finished-powder testing only for *Salmonella* and *Cronobacter* — and nothing for *Clostridium botulinum*[10] — three years after the agency named the organism in its own letter to industry?

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[8] Infant Formula Safety Modernization Act of 2026, H.R. 7867, 119th Cong. (2026), congress.gov/bill/119th-congress/house-bill/7867. Sponsored by Rep. Rosa DeLauro and co-led by Rep. Jeff Van Drew; referred to the House Committee on Energy and Commerce, with a Subcommittee on Health hearing held April 29, 2026.

[9] FDA, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)*, June 26, 2026 update (traceback finding that the implicated Nara lots were made with milk supplied by Organic West Milk and spray-dried by Dairy Farmers of America — the same suppliers behind the ByHeart outbreak — and that the customer list Organic West provided during the 2025 ByHeart investigation did not include Nara), fda.gov; see also William D. Marler, *FDA Confirms the Shared Suppliers — but Hasn't Linked them to the Nara Illnesses — Yet* (June 26, 2026), Marler Blog, marlerblog.com.

[10] 21 C.F.R. § 106.55 (microbiological testing of powdered infant formula limited to *Salmonella* and *Cronobacter*; no standard for *Clostridium botulinum*), ecfr.gov.

2. **Questions to Dairy Farmers of America:** What did you know about the risk of using powdered whole milk in infant formula? What did DFA know about the whole-milk-powder it dried for both brands; what testing did it perform for spore-forming organisms; and what did it disclose, and to whom, during the ByHeart trace-forward?
3. **Questions to Organic West Milk:** What did you know about the risk of using whole milk in infant formula? Why was Nara left off the customer list provided to the FDA in 2025? Who prepared that list, who reviewed it, and when did Organic West first know that the same milk supply had reached a second infant-formula brand?
4. **To Nara Organics:** What did you know about the risk of using whole milk in infant formula? When did Nara learn that its whole-milk-powder came through the same Organic West/DFA supply stream implicated in the ByHeart outbreak; what did it test for; and what did it tell regulators and parents — and when?

The common thread running through all four is a single question this Committee is uniquely positioned to ask in public: **why was the shared milk and powdered-milk supply not disclosed in 2025, when disclosure could have prevented the second outbreak entirely?**

I have spent a career watching companies answer that kind of question only when a courtroom compels them. Discovery and depositions will force a complete record in the litigation I am handling. But the public-policy record — the record that tells you whether the law needs to change — belongs to you. A hearing reaches witnesses, and asks questions, that no single plaintiff's case can.

My second ask: hold hearings. *Bring the FDA, Dairy Farmers of America, Organic West Milk, and Nara Organics before this Committee and put the disclosure failure of 2025 on the public record — so the next reform is built on what actually happened, not on what anyone is willing to volunteer.*

It is time for the parents to testify

There is one more thing, and to me it is the most important. Throughout this episode, the people with access to the rooms where decisions get made have been the companies and the agencies. The Secretary of Health and Human Services has met with formula-company chief executives more than once. The FDA has convened industry roundtables. The one group that has not been in the room — not in any room that counts — is the parents.

I represent those families. They followed every instruction on the label and watched a two-month-old go limp in their arms. They spent weeks in pediatric intensive care not knowing whether their child would breathe on his own again. One family was flown by medevac from Idaho to a children's hospital in Utah. Several of them have already written statements for Congress; I attached those statements, in their own words and with their own photographs, to my June 23, 2026 letter to the House Committee on Energy and Commerce. They are willing to do more than write. They are willing to come and testify.

When this Committee marks the human cost of a policy failure, no expert and no lawyer — myself included — can substitute for the parent who lived it. These mothers and fathers can tell you, better than any of us, what "safe" turned out to mean when the system tested for too little, too late, and told too few people when something went wrong.

My third ask: invite the parents to testify. *Give the families of the ByHeart and Nara infants a seat at the witness table before this Committee writes the next chapter of infant-formula safety law. They have earned it the hardest way there is.*

We have done this before

The Jack in the Box tragedy moved the USDA to declare *E. coli* O157:H7 an adulterant in ground beef in 1994 — a single decision that has kept countless children out of hospital beds in the decades since.[11] This Committee, and this Senate, have the same kind of window open right now. You proved on April 29 that the consensus exists. I am asking you to extend it the one further step these two outbreaks demand: pass a bill that reaches botulism, hold the hearings that put the 2025 disclosure failure on the record, and let the parents speak.

Thank you for your leadership on S. 272, and for your consideration of what I believe the moment now requires.

Very truly yours,



William D. Marler

WDM:jd

[11] USDA, Food Safety & Inspection Service (in August 1994 FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef), fsis.usda.gov.

3. Letter to this Committee of
August 28, 2026

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August 28, 2026

The Honorable Bill Cassidy, M.D., Chairman
The Honorable Bernie Sanders, Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC 20510

Re: The genetic link confirmed on August 27, 2026 between the ByHeart and Nara Organics infant botulism outbreaks — and why the three requests in my June 29 letter now have an evidentiary answer

Dear Chairman Cassidy, Ranking Member Sanders, and Members of the Committee:

I wrote to you on June 29, 2026 about botulism in powdered infant formula.[1] I asked three things: that the Senate take up legislation reaching *Clostridium botulinum*, that this Committee hold hearings on how the same contaminated milk supply reached a second brand, and that the parents of the injured infants be given a seat at the witness table. I have had no reply. I am writing again because yesterday the federal government answered the question my June letter could only ask.

What the government said yesterday

On August 27, 2026, the Centers for Disease Control and Prevention declared the Nara Organics outbreak over.[2] When I wrote to you in June the outbreak stood at three confirmed infants. The agencies added a fourth as the investigation continued, and four is the final count — in California, Pennsylvania and Washington, with illness onsets on April 20, May 17, May 20 and May 31, 2026. All four were hospitalized. None died.

CDC did not close the file with a hedge. It found that epidemiologic, traceback and laboratory data showed that Nara Organics Whole Milk Organic Infant Formula was contaminated with *Clostridium botulinum* and made infants sick. Its earlier update had said only that the formula *might* be contaminated. The agency dropped the qualifier.

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[1] William D. Marler, *Letter to the Committee on Health, Education, Labor, and Pensions* (June 29, 2026), Marler Blog, marlerblog.com.

[2] Centers for Disease Control and Prevention, *Infant Botulism Outbreak Linked to Powdered Infant Formula, June 2026* (update of Aug. 27, 2026), cdc.gov. Investigation status reported as closed; four cases, four hospitalizations, no deaths, three states.

Then came the finding that should bring this Committee back to the subject. Whole genome sequencing linked a patient sample from the Nara outbreak to a patient sample, product samples and an ingredient sample collected during the investigation of the 2025 ByHeart outbreak.[3] The FDA describes the same result more specifically, reporting a match to a ByHeart clinical sample, a powdered infant formula base sample, and four samples of unopened cans of ByHeart formula.[4] CDC states that FDA's traceback determined that the infant formulas sold by *both* Nara Organics and ByHeart were made with milk supplied by Organic West Milk and spray dried by Dairy Farmers of America, and that the matching sequences indicate a common source of contamination for the two outbreaks.

One qualification, which you should hear from me rather than from someone across a table. Neither agency has determined a root cause, and FDA says it does not yet have enough evidence to decide whether the milk was contaminated before it was dried or during the drying process. That open question governs which company bears what share of the responsibility. It does not touch whether the formula was contaminated, and it does not touch whether the formula paralyzed babies. CDC decided both of those yesterday.

In June this was an inference. It is now a laboratory finding.

My June letter told you that the two outbreaks shared a supply chain and that the contamination did not strike two companies by chance. That was reasoning from a traceback. It is no longer reasoning. The same organism has now been found in an infant fed one brand and in the product and the ingredient of the other. A strain does not travel between two babies who never consumed the same product by accident. It travels through the thing they shared, and the only thing these two shared was an ingredient.

That is what turns the disclosure failure I described in June from a procedural lapse into a measurable one. During the 2025 ByHeart investigation the FDA ran the trace-forward the playbook calls for and asked Organic West Milk who else it supplied. The customer list did not include Nara Organics, and Organic West has since told the FDA that it should have.[5] ByHeart recalled all of its product on November 11, 2025. CDC declared that outbreak over on February 26, 2026. The first Nara infant became ill on April 20, 2026 — 160 days after the recall, and 53 days after the government told the country the first outbreak was finished. The one mechanism designed to prevent a second outbreak existed, the agency used it, and an incomplete answer defeated it. We now know, at the level of the genome, what got through.

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[3] CDC, *Investigation Update on Infant Botulism Outbreak, June 2026* (Aug. 27, 2026), cdc.gov (whole genome sequencing link to the 2025 ByHeart investigation; traceback finding that the formulas sold by both brands were made with milk supplied by Organic West Milk and spray dried by Dairy Farmers of America; and the statement that FDA does not have enough evidence to determine whether the milk was contaminated before or during drying).

[4] U.S. Food and Drug Administration, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)* (update of Aug. 27, 2026), fda.gov.

[5] FDA, *Post-Outbreak Response Activities: Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula*, fda.gov (trace-forward conducted during the 2025 ByHeart investigation; customer list provided by Organic West Milk did not indicate that its milk was supplied to the manufacturers of Nara Organics infant formula; Organic West Milk subsequently informed FDA that the information should have included Nara Organics). Page stated as current as of July 13, 2026.

Fifty-two infants, and the regulation still does not name the organism

Forty-eight babies in the ByHeart outbreak. Four in the Nara Organics outbreak. Fifty-two infants hospitalized across the two outbreaks, many of them on ventilators, each treated with BabyBIG antitoxin that the State of California prices at $69,300 a dose.[6]

Nothing in the law has changed. Federal regulation still requires microbiological testing of powdered infant formula for *Salmonella* and *Cronobacter* and says nothing about *Clostridium botulinum*.[7] S. 272, which this Committee reported 22 to 0 and the full Senate passed by unanimous consent on April 29, requires one-business-day notice for the organisms already on that list — which does not include the one that paralyzed these fifty-two children.[8] The FDA named *Clostridium botulinum* by genus and species in a Call-to-Action letter to the entire powdered infant formula industry on March 8, 2023, three and a half years ago.[9] Since these outbreaks began the agency has written to industry, referred questions to international scientific bodies, and held a public meeting. Letters and referrals are not a rule, and the sequencing result released yesterday is the strongest evidence yet that a rule is what this requires.

The three requests from June, renewed — and one more

First, pass a bill that reaches botulism. H.R. 7867, the Infant Formula Safety Modernization Act of 2026, names the organism on the testing list, requires environmental monitoring inside the plant, and holds foreign manufacturers to American standards. Take up a companion measure, or write your own. The gap S. 272 left open is now the only gap that has actually put babies in intensive care.

Second, hold hearings. Bring the FDA, Dairy Farmers of America, Organic West Milk, Nara Organics and ByHeart before this Committee. The questions are sharper than they were in June, because there is now a laboratory result to ask about. How long has this organism been in this ingredient stream? Who tested for it, with what method, and how often? What did each company know after November 2025, and what did each one do about it?

Third, invite the parents to testify. They followed every instruction on the label and watched an infant go limp in their arms. Several have already written statements for Congress. They are willing

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[6] California Dep't of Public Health, Infant Botulism Treatment & Prevention Program, *BabyBIG® Fee Schedule* — $69,300 per dose (eff. July 1, 2025), cdph.ca.gov. Case totals: 48 infants in 17 states in the ByHeart outbreak, FDA, *Outbreak Investigation of Infant Botulism: Infant Formula (November 2025)*, fda.gov; four infants in the Nara Organics outbreak, CDC, supra note 11.

[7] 21 C.F.R. § 106.55 (microbiological testing of powdered infant formula limited to *Salmonella* and *Cronobacter*; no standard for *Clostridium botulinum*), ecfr.gov.

[8] FDA, *FDA's Actions to Respond to Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula* (discussing the March 8, 2023 Call-to-Action letter to the powdered infant formula industry, signed by the Commissioner of Food and Drugs and the Director of CFSAN, naming *Clostridium botulinum*), fda.gov; letter text at fda.gov/media/166044/download.

[9] Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), congress.gov (reported favorably by this Committee 22–0 and passed by the full Senate by unanimous consent on April 29, 2026); Infant Formula Safety Modernization Act of 2026, H.R. 7867, 119th Cong. (2026), congress.gov (sponsored by Rep. Rosa DeLauro and co-led by Rep. Jeff Van Drew; referred to the House Committee on Energy and Commerce).

to come and say it in person. No expert and no lawyer, myself included, can substitute for the parent who lived it.

Fourth, and this one is new: put a written question to the FDA, with a deadline. The agency's root cause investigation has been open since November 2025. Its own public page on this subject has not been updated since July 13, 2026 and still says there is not enough evidence to determine whether the shared suppliers are the source of the contamination — language its own sequencing has now overtaken. Ask the Commissioner what the root cause investigation has found; whether the agency intends to require testing or environmental monitoring for *Clostridium botulinum* by regulation; and if so, on what schedule. A date certain would tell this Committee whether legislation is necessary or merely useful. The absence of one would tell you something too.

We have done this before

The Jack in the Box tragedy moved the USDA to declare *E. coli* O157:H7 an adulterant in ground beef in 1994 — one decision that has kept countless children out of hospital beds in the decades since.[10] You proved on April 29 that the consensus on infant formula exists in this body. Two months ago I asked you to extend it one step further. Yesterday the government supplied the evidence that the step is necessary. Fifty-two families already know what the sequencing means. They would like to know that the Senate does too.

Thank you for your leadership on S. 272, and for your consideration of what the record now shows.

Very truly yours,



William D. Marler

WDM:jd
Enclosure: Letter to this Committee of June 29, 2026

[10] USDA, Food Safety & Inspection Service (in August 1994 FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef), fsis.usda.gov.