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November 4, 2026

The Honorable Brett Guthrie, Chairman
The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Re: H.R. 7867 and S. 272 after Tuesday's election — the gavel changes hands in January and the arithmetic does not; a request to finish the infant formula botulism bill in the weeks the 119th Congress has left, and an offer to bring the families to your offices

Dear Chairman Guthrie, Ranking Member Pallone, and Members of the Committee:

I have written to this Committee twice about botulism in powdered infant formula: on June 23, with the statements and photographs of fourteen families attached, 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 and of its Senate counterpart.[2] What it did not change is a single fact in the two letters

[1] William D. Marler, *Support for H.R. 7867, the Infant Formula Safety Modernization Act of 2026* (June 23, 2026) (letter to this Committee, with Appendix A — statements and photographs of affected ByHeart and Nara families), www.marlerblog.com/case-news/support-for-h-r-7867-the-infant-formula-safety-modernization-act-of-2026/; William D. Marler, *H.R. 7867 Follow-Up Letter* (Aug. 28, 2026), www.marlerblog.com/files/2026/08/HR7867_Follow_Up_Letter_8-28-26.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*

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] H.R. 7867, the bill that would put it there, has sat in this Committee since its April 29 hearing without a markup. 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.

H.R. 7867 was introduced by Rosa DeLauro, a Democrat, and is co-led by Jeff Van Drew, a Republican.[5] S. 272, the Protect Infant Formula from Contamination Act, was introduced by Gary Peters, a Democrat, and John Hoeven, a Republican; the Senate HELP Committee reported it 22 to 0, and the full Senate passed it by unanimous consent in April.[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 the

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midterms as Democrats decisively win control of House and Senate, www.cbsnews.com/live-updates/election-day-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] 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.

[6] 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.

[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.

Senate HELP Committee in June and on my own blog the day the nutrient rule was announced.[8] When Senator Cassidy, a Republican, demanded answers from ByHeart in December and from Nara Organics in July, I said publicly that he was right to.[9] Four years ago, when a contaminated plant in Sturgis, Michigan emptied the nation's formula shelves, this House passed the Access to Baby Formula Act 414 to 9, the 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 Congress 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 fifty-four offices on this Committee, and one went to every other member of

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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 the Senate HELP Committee of June 29, 2026, 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.

Congress.[12] They read: For Babies' sake, Test for Botulism in Infant Formula. If one is still on a desk in Rayburn, it still says the whole argument in one line.

The FDA, for its part, 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.

I raise the petition here for a reason. Everything in it is something Congress can order by statute, or press the agency to do by regulation at a hearing. The petition is the administrative route; H.R.

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[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 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).

7867 is the legislative one. A Committee that wanted these babies protected by spring could take either.

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.[15] On January 3, every bill that has not been enacted dies, H.R. 7867 and S. 272 among them. There are three ways to finish this before then, and I would take any of them.

The first is the one I have asked for since June: mark up H.R. 7867 and report it. The Subcommittee on Health held its hearing on April 29. The markup is the only step missing.

The second is already sitting at the Speaker's desk. S. 272 passed the Senate in April, was received in the House on May 4, and has been held at the desk since, which means it can be brought to the floor without a referral to this Committee.[16] As written it reaches only the organisms already on the § 106.55(e) list; the word botulism appears in it twice, both times inside a list of things the Secretary's reports, due one, three and five years after enactment, "may include." But its one-business-day notice duty is drafted to follow that list "or any successor regulation," so it reaches *Clostridium botulinum* the day the FDA adds the organism to its own table. The House can pass S. 272 as it stands and have it signed before Christmas, or amend it with the testing language of H.R. 7867 and send it back to a Senate that passed the subject in April without a single objection.

The third is the oldest route on the Hill. H.R. 7867 is a few pages long. It rides on anything that must pass before December 11.

If none of the three happens, I am asking both of you to reintroduce the bill on the first day of the 120th Congress with both your names on it, whichever of you holds the gavel. I will write the same letter to the same two people 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

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[15] 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.

[16] S. 272, supra note 6 (received in the House and held at the desk, May 4, 2026). The Senate-passed text ties the notice duty to "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)," S. 272 § 2 (new 21 U.S.C. § 350a(e)(2)), and 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)).

in the whole milk powder.[17] A sentence adding the dairy ingredient to the testing requirement in section 2(a) would reach the place the spores actually entered. The enclosed petition has the language.

What I am asking, renewed, with one addition

First, finish the bill before January 3, by any of the three routes above, and reintroduce it on January 4 if you cannot.

Second, hold the oversight hearing. Bring the FDA, Dairy Farmers of America, Organic West Milk, Nara Organics and ByHeart before this Committee. The questions have not changed since August and they have not been answered: how long the organism has been in this ingredient stream, who tested for it and how, and why a supplier's customer list handed to the FDA during the first outbreak left off the brand that caused the second.

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, put the parents at the witness table. Fourteen of them wrote to you in June, 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. The Senate needed one afternoon in April. This bill has been in front of this Committee for eight months, 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. The families would like to know that this Committee can finish a bill that both parties wrote.

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[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.

Thank you for your consideration, 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 23, 2026, with Appendix A — statements and photographs of affected families
3. Letter to this Committee of August 28, 2026

cc: The Honorable Rosa DeLauro
The Honorable Jeff Van Drew

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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McKenzie Ksobiech
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/s/ Anit Joseph
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/s/ Aman Chughtai
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/s/ Tooba Chughtai
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/s/ Kieley Weaver
Kieley Weaver

/s/ Cole Weaver
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/s/ Madi Wescott
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/s/ Erica Goldfin
Erica Goldfin

/s/ 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

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21 CFR 10.30, 25.30(j), 106.6, 106.55, 106.150; 21 CFR part 117.

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

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A. Edney, Bloomberg News, reporting MeridianMade's agreement to acquire Perrigo's infant formula business (Oct. 29, 2026).

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Food Safety Authority of Ireland, Danone infant formula and follow-on formula recall (Jan. 2026); U.K. Food Standards Agency, FSA-PRIN-02-2026, FSA-PRIN-03-2026, FSA-PRIN-05-2026.

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

Follow-up letter to the Committee on Health, Education, Labor, and Pensions, August 28, 2026. https://www.marlerblog.com/files/2026/08/Senate_HELP_Follow-Up_Letter_8_28_26_WDM.pdf

2. Letter to this Committee of June 23, 2026 with Appendix A-statements and photographs of affected families.

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June 23, 2026

The Honorable Brett Guthrie, Chairman
The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Re: Support for H.R. 7867, the Infant Formula Safety Modernization Act of 2026

Dear Chairman Guthrie, Ranking Member Pallone, and Members of the Committee:

I write in support of H.R. 7867, the Infant Formula Safety Modernization Act of 2026.

For more than thirty years — since the 1993 Jack in the Box *E. coli* outbreak — I have represented children and families sickened by food they trusted. I now represent babies who fell ill with botulism in the first few months of their lives because of tainted infant formula. The attachment to this letter contains their stories—of pain, survival, and preventable harm.

The hard arithmetic of my work is that reform rarely arrives until enough people are hurt to force it. The Jack in the Box tragedy[1] is what moved USDA to declare *E. coli* O157:H7 an adulterant in ground beef in 1994[2] — a single decision that has kept countless children out of hospital beds in the decades since.

This Committee has the same kind of window open right now to make infant formula safe, and this bill is the right response.

Two *botulism* outbreaks in seven months — and a longer pattern behind them

In November 2025, *Clostridium botulinum* in ByHeart Whole Nutrition Infant Formula — a whole-milk-powder product — was tied to an infant *botulism*[3] outbreak that ultimately sickened 48 infants across 17 states. Every infant was hospitalized. I represent more than twenty of those families. FDA's whole-genome sequencing matched the organism across a clinical isolate, a closed

[1] Over 600 sick, over 50 with acute kidney failure and four dead children.
[2] 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."), https://www.fsis.usda.gov/node/2003.
[3] Infant botulism is a rare but serious illness caused when spores of *Clostridium botulinum* grow in a baby's intestine and produce toxin that weakens muscles, https://www.cdph.ca.gov/Programs/cls/idld/ibtpp/Pages/InfantBotulism.aspx.

can of finished formula, and the incoming ingredient — organic whole milk powder. It also matched it to a Blendhouse facility tied to that supply chain that had already been flagged "Official Action Indicated," FDA's most serious inspection classification, before these babies were ever hurt.[4]

Seven months later it happened again. In June 2026, three more infants — in California, Pennsylvania, and Washington, all between two and five months old — were hospitalized with *botulism* and treated with BabyBIG antitoxin after consuming Nara Organics Whole Milk Organic Infant Formula, a product manufactured abroad and sold here through national retail.[5]

And these two outbreaks were not merely alike — they shared a common source. The whole milk behind the contaminated ByHeart formula and the whole milk behind the Nara formula came from the same supplier; one upstream source furnished both the fluid milk and the powdered milk that went into these products.[6] The contamination did not strike two unrelated companies by chance; it traveled through one shared supply stream that the system missed the first time and missed again — the clearest proof that the gap this bill closes sits upstream, at the milk and the plant, exactly where H.R. 7867 directs the testing.

A second *botulism* outbreak in the same year, in the same category of product, was foreseeable. We had just lived through the first and the system did nothing in between. The pattern is older still: we knew about *Cronobacter* bacteria for two decades before contamination at Abbott's Sturgis plant in 2022 took infant lives and triggered a national infant formula shortage.[7] The thread is not bad luck. It is a system that tests for too little, too late, and tells too few people when something goes wrong.

And these were not faraway statistics or someone else's constituents. The ByHeart outbreak reached infants in seventeen states — among them Arizona, California, Idaho, Illinois, Kentucky, Massachusetts, Michigan, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode

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[4] U.S. Food & Drug Admin., FDA's Actions to Respond to Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula (2026) (whole-genome sequencing linked the strain across the clinical isolate, finished formula, and the incoming whole milk powder), https://www.fda.gov/food/outbreaks-foodborne-illness/fdas-actions-respond-clostridium-botulinum-illnesses-associated-consumption-powdered-infant-formula. The case totals (48 infants in 17 states; 28 confirmed, 20 probable) and the "Official Action Indicated" designation — the agency's most serious inspection classification — are reflected in FDA's Outbreak Advisory and in the bill sponsor's summary, https://delauro.house.gov/media-center/press-releases/delauro-introduces-bipartisan-infant-formula-safety-modernization-act.

[5] U.S. Food & Drug Admin. & Centers for Disease Control & Prevention, investigation of infant botulism associated with Nara Organics Whole Milk Organic Infant Formula (June 2026); see also note 2, supra. Three infants in California, Pennsylvania, and Washington, ages two to five months, were hospitalized with type A botulism and treated with BabyBIG®.

[6] Helena Bottemiller Evich, *Federal Court Halts SNAP Restriction Pilots in Five States*, Food Fix (June 23, 2026) (reporting that the Nara Organics formula and the ByHeart formula shared the same whole milk supplier), https://foodfix.co/federal-court-halts-snap-restriction-pilots-in-five-states/.

[7] See Rep. Rosa DeLauro, DeLauro Introduces Bipartisan Infant Formula Safety Modernization Act (Mar. 2026) (Abbott Nutrition's Sturgis, Michigan facility, then responsible for roughly 40% of domestic formula production, shut down in 2022 following Cronobacter contamination, triggering a national shortage), https://delauro.house.gov/media-center/press-releases/delauro-introduces-bipartisan-infant-formula-safety-modernization-act.

Island, Texas, Virginia, Washington, and Wisconsin[8] — and the June 2026 Nara outbreak struck families in California, Pennsylvania, and Washington, each of them represented by a member of this Committee. The children paralyzed by contaminated infant formula are the children of the families you serve.

The hazard was on the government's own record — in writing — years in advance

On March 8, 2023 — two years before the first ByHeart baby became ill — the FDA sent a Call-to-Action letter to every manufacturer, packer, distributor, importer, and retailer of powdered infant formula in the country, signed by the Commissioner of Food and Drugs and the Director of the agency's food-safety center. It named the organism by genus and species, instructing the industry to account for the historical association between powdered infant formula and pathogens including *Cronobacter*, *Salmonella*, and *Clostridium botulinum* when designing safety controls[9].

In March 2025, under Operation Stork Speed,[10] FDA announced it would increase testing of formula and its ingredients for spore-forming contaminants — naming *C. botulinum* specifically — and by early 2026 it had opened a sampling assignment aimed at exactly the ingredients at issue: whole milk powder, nonfat dry milk, and whey.[11] The science is not obscure: *C. botulinum* is a spore-former whose spores survive ordinary pasteurization and spray-drying and live in soil and dust. That is precisely why the controls must start with the milk and the plant — upstream, where the spores enter — and cannot end with a reassuring number on a finished can.

Guidance has already been tried — and it failed twice.

The FDA named *botulism* in writing in 2023 and folded spore-forming pathogens into Operation Stork Speed in 2025, yet it never required anyone to test whole-milk-powder formula for *botulinum* before shipping it. Two outbreaks followed. The lesson is not that the agency needs another guidance letter or another voluntary initiative — either of which can be quietly shelved when budgets tighten or administrations change — but that the duty to test must be written into law, where it is durable and enforceable. Nor is the testing impractical: after these outbreaks,

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[8] The 48 infants in this outbreak were reported from 17 states: Arizona, California, Idaho, Illinois, Kentucky, Massachusetts, Michigan, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, Virginia, Washington, and Wisconsin. CDC, Investigation Update: Infant Botulism Outbreak (Feb. 26, 2026), https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/investigation.html.

[9] U.S. Food & Drug Admin., 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"), https://www.fda.gov/media/166044/download; see also FDA, FDA Calls for Enhanced Safety Measures in Letter to Powdered Infant Formula Industry (Mar. 2023), https://www.fda.gov/food/hfp-constituent-updates/fda-calls-enhanced-safety-measures-letter-powdered-infant-formula-industry.

[10] U.S. Dep't of Health & Human Servs. & FDA, HHS, FDA Announce Operation Stork Speed (Mar. 18, 2025), https://www.fda.gov/news-events/press-announcements/hhs-fda-announce-operation-stork-speed-expand-options-safe-reliable-and-nutritious-infant-formula; see FDA, Operation Stork Speed, https://www.fda.gov/food/infant-formula-homepage/operation-stork-speed.

[11] U.S. Food & Drug Admin., FDA's Actions to Respond to Clostridium botulinum Illnesses… (note 2, supra) (FDA "initiated additional sampling of dairy-based ingredients, including whole milk powder, nonfat dry milk powder, and whey protein concentrate").

manufacturers began screening for spore-formers on their own. Nara itself quietly added "spore-forming organisms" to its published testing list after its recall. If industry can test for this hazard once babies are hurt, it can test for it before a single can ships. H.R. 7867 simply makes the timing mandatory rather than optional.

The economics favor this bill as strongly as the ethics do. A single dose of BabyBIG — the antitoxin that is the only treatment for infant botulism — costs $69,300[12] per dose (some need at least two) and every one of the 48 ByHeart and three Nara infants needed it. Add to that the intensive-care stays, the air-ambulance transports — one family in the appendix was flown by medevac from Idaho to a children's hospital in Utah — the months of feeding tubes and physical therapy, the nationwide recalls, the plant shutdowns, and the litigation that inevitably follows. Routine pathogen and environmental testing costs a small fraction of a single dose of the cure. This is the rare safety mandate that saves money — for families, for hospitals, for insurers, and for the public programs that ultimately absorb these costs.

What the bill does — Each fix mapped to a failure we have already seen

I have read every line of H.R. 7867.[13] It is sober, specific, and it closes the exact gaps that let these babies get hurt. It does six concrete things:

1. **Expands required pathogen testing.** Current rules effectively require finished-formula testing only for *Cronobacter* and *Salmonella*;[14] *C. botulinum* was not on the list — which is precisely how two botulism outbreaks slipped through. The bill directs FDA to build a real list and names *C. botulinum* on it.

2. **Mandates environmental testing inside the plant.** Standardized monitoring of Zones 2 and 3 catches contamination in the production environment before it ever reaches a can — standard practice elsewhere in food manufacturing but not required by law for the food we feed newborns.

3. **Sets consistent standards.** FDA, not each company, sets the testing frequency — so "we tested" means the same thing at every facility instead of each manufacturer grading its own work.

4. **Requires early notification — within one business day of a positive test, even before product leaves the building.** This is the provision that matters most in a *botulism* event. Today a company can get a positive result and sit on it while product lingers on shelves; mandatory

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[12] California Dep't of Public Health, Infant Botulism Treatment & Prevention Program, BabyBIG® Fee Schedule, $69,300 per dose (eff. July 1, 2025), https://www.cdph.ca.gov/Programs/OLS/CDPH%20Document%20Library/DPH-25-005-BabyBIG_Fee_FP.pdf; see Infant Botulism Treatment & Prevention Program, https://www.infantbotulism.org.

[13] Infant Formula Safety Modernization Act of 2026, H.R. 7867, 119th Cong. (2026), https://www.congress.gov/bill/119th-congress/house-bill/7867; bill text at https://delauro.house.gov/sites/evo-subsites/delauro.house.gov/files/evo-media-document/infant-formula-safety-modernization-act-of-2026.pdf.

[14] The current testing requirement reaches only Cronobacter spp. and Salmonella. See 21 C.F.R. § 106.55; 21 C.F.R. pts. 106–107 (infant-formula quality-control and testing requirements). The regulations do not require testing for Clostridium botulinum.

early notice shrinks the gap between when the company knows and when parents do — a gap measured in hospitalized infants.

5. **Holds foreign manufacturers to the same standards.** ByHeart's *botulinum* rode in on a home-grown ingredient. While the Nara formula behind the second outbreak was made abroad, for at least a period, it used a US-grown ingredient and same suppliers as ByHeart. Either way, if it is sold to an American baby, it should meet American testing requirements.

6. **Strengthens Congressional oversight.** The bill requires notice to Congress of any confirmed positive in finished formula and any "Official Action Indicated" inspection finding. That "Official Action Indicated" finding already existed in the ByHeart supply chain and went nowhere without Congressional oversight.

The bill also gives FDA 90 days to finalize the rules. We have waited long enough.

The bill will protect the formula supply, not threaten it. Some will warn that more testing means more recalls and another 2022-style shortage. The opposite is true. Contaminated formula is the supply crisis: it was a contaminated plant in Sturgis that emptied the nation's shelves in 2022, and it is undetected pathogens — not the tests that catch them — that force the largest recalls and the longest shutdowns. Catching contamination upstream, before a single can ships, is how this Committee keeps safe formula on the shelf. Safety and supply are not a trade-off; they are the same fight.

Bipartisan, broadly endorsed, and overdue. Protecting infants from contaminated formula is not a left-or-right question. H.R. 7867 is led by Representative Rosa DeLauro and joined by Representative Jeff Van Drew, and it is endorsed by the American Academy of Pediatrics, Consumer Reports, the Consumer Federation of America, the Center for Science in the Public Interest, the Environmental Working Group, STOP Foodborne Illness, the Association of Public Health Laboratories, and Prolacta.[15] That the American Academy of Pediatrics — the physicians who actually stand at these infants' bedsides — has put its name to this bill should carry particular weight: it is the considered judgment of the people who treat the disease. Every provision in this bill is something that, had it been law a year ago, might have meant fewer of the families in the appendix to this letter ever needing to suffer.

The Senate has already acted — now the House must finish the job. On April 29, 2026, the Senate passed the Protect Infant Formula from Contamination Act, S. 272, by unanimous consent — bipartisan legislation introduced by Senators Gary Peters and John Hoeven and reported out of the Health, Education, Labor, and Pensions Committee by a vote of 22 to 0.[16] That a measure to

[15] H.R. 7867 is sponsored by Rep. Rosa DeLauro (D-CT) and co-led by Rep. Jeff Van Drew (R-NJ); endorsing organizations are listed in the sponsor's release, https://delauro.house.gov/media-center/press-releases/delauro-introduces-bipartisan-infant-formula-safety-modernization-act. The bill was referred to this Committee and received a legislative hearing before the Subcommittee on Health on April 29, 2026.

[16] Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), https://www.congress.gov/bill/119th-congress/senate-bill/272. The Senate passed S. 272 by unanimous consent on April 29, 2026; the Senate Committee on Health, Education, Labor, and Pensions had earlier reported the bill favorably by a vote of 22–0. See Press Release, Sen. Gary Peters, Senate Passes Peters' Bipartisan Legislation to Prevent Infant Formula Shortages (Apr. 29, 2026), https://www.peters.senate.gov/newsroom/press-releases/senate-

close the infant-formula notification gap cleared the other chamber without a single dissenting voice is proof that this is neither a partisan question nor a close one. But S. 272 reaches only the contaminants already on the books — *Cronobacter* and *Salmonella* — and would not have caught the *Clostridium botulinum* that paralyzed the infants whose parents speak in the appendix to this letter. It is the narrower bill. H.R. 7867 is the one that names *botulism* on the testing list, mandates environmental monitoring inside the plant, and holds foreign manufacturers to American standards. The Senate has shown the consensus is there; this Committee can finish what the Senate started — and take the one further step these two outbreaks demand.

We have seen this turn out well before. We turned the Jack in the Box tragedy into a rule that made hamburger safer for a generation of children. This Committee can do the same for the formula we feed newborns. The Subcommittee on Health has already held its hearing on this bill; the next step is to act on it. I respectfully urge the Committee to markup H.R. 7867 and report it favorably.

I note, with no small alarm, that the second *botulism* outbreak arrived while this very bill was already pending before you: Nara's babies were hospitalized in the spring of 2026, after H.R. 7867 was introduced in March and after its April 29 hearing. The cost of waiting is no longer hypothetical.

The appendix that follows is the real heart of this letter. These are the infants harmed in the ByHeart and Nara outbreaks, in their parents' own words — statements many of these families wrote for Congress. I ask you to read them, and to keep these children in mind as you consider this bill.

Very truly yours,



William D. Marler

WDM:jd
Enclosure: Appendix A — Statements and photographs of affected families

passes-peters-bipartisan-legislation-to-prevent-infant-formula-shortages. S. 272 amends 21 U.S.C. § 350a(e) to require one-business-day notification of confirmed positive finished-product tests for the microorganisms already covered by 21 C.F.R. § 106.55(e) — *Cronobacter* and *Salmonella* — and does not reach *Clostridium botulinum*.

APPENDIX A

"From Botulism Babies and Parents"

Infants of the ByHeart and Nara outbreak — in their parents' own words

The statements below were written by the parents of children sickened in the 2025 ByHeart and 2026 Nara infant botulism outbreaks and several were first shared publicly in connection with testimony to Congress. Each is reproduced as the family wrote it. Photographs of the children accompany each statement, with the families' permission.

Baby 1 — *in the parents' words*



"When our six-month-old son was diagnosed with infant botulism, our world stopped. Watching our baby, who should have been learning, growing, and thriving – was suddenly facing a life-threatening condition, which is something no parent is prepared for. In the span of three days, our healthy baby boy exhibited failure to thrive, as he lost function of his motor skills, was unable to swallow, and his digestive tract was impacted. The fear and helplessness of seeing our child suffer and not knowing if he would recover or what long-term effects such as paralysis, respiratory issues, or even death that he might face, is a trauma that will stay with us forever.

What makes this experience even harder to accept is knowing it may have been prevented. Families should not have to endure this kind of trauma due to preventable risks or corporate negligence. Companies must be held accountable for their role in protecting the health and safety of the most vulnerable, especially infants who have no voice of their own.

We believe it is critical that Congress understands the real human cost behind cases like ours. We urge Congress to recognize these failures and to hold companies fully accountable for their role in protecting infants and families. Strong action can spare other families from enduring the fear, heartbreak, and lasting trauma that ours has endured. No parent should ever have to watch their child fight for their life because of failures that could have been avoided."

Baby 2 — *in the parents' words*



"It's been a nightmare." That's what I find myself saying to friends and acquaintances after sharing the story of what happened to my son over the last three months. What began as a slow, but noticeable weight loss and decreased feeds in late October quickly spiraled into a lengthy hospitalization with multiple readmissions for various setbacks and complications. Silent aspiration, oxygen levels in the low 80s, inability to feed from a bottle normally, the inability to hold his head up, and the inability to breath without oxygen. These are some of the complications he encountered.

The darkest day was the day he got air-flighted from Flagstaff to Phoenix Children's Hospital. That's when the realization hit that my previously perfect baby was very seriously ill. It was just two days after that when they told us our son had had three small strokes in the back of his brain. After finally getting treated with Baby BIG, the antitoxin for infant Botulism, we noticed dramatic improvements in our son's ability to hold his head up within just 2-3 days. We are thankful for this life-saving treatment. I understand the cost of Baby BIG is just over $69,000 for one dose. I can't help but wonder how different our lives would be, how different his life would be, if manufacturers were required to screen for microorganisms like Botulism and Cronobacter. The cost of screening is surely less than the antitoxin for Botulism, and with Botulism diagnoses on the rise something needs to be done to prevent another family from going through what we've endured.

The ripple effect has affected not just our son, but also his parents, his brother, his grandparents, aunts, uncle, friends and neighbors. It's taken an entire community who rallied together to get us to the place we are in today, which is a place of uncertainty, but also hope. He is still fed through an NG tube and any formula he eats by mouth has to be thickened so he doesn't aspirate it into his lungs. We are hopeful he will make a full recovery in time, but I still mourn all that's been lost in our new baby experience from this illness."

Baby 3 — *in the parents' words*



"As for a statement, this experience was the hardest thing my wife and I have ever been through. Our daughter changed so much overnight and kept getting worse. She had no energy, could barely move or open her eyes, couldn't hold her head up or eat or drink. We had to take her to the hospital 4 times before someone suspected botulism. We didn't know if she was going to survive.

She was in the hospital for 3 weeks but has required many follow up visits with her doctor and other specialists. She still hasn't fully recovered and will require more visits with doctors and physical therapists to get her development back on track. My wife and I have had to take a lot of time off from work and this situation has had a tremendous effect on our mental and emotional state. We will do whatever we have to in order for our daughter to recover, but it hasn't been easy."

Baby 4 — *in the parents' words*



"I am one of the many parents directly impacted by the ByHeart infant formula botulism contamination. As a parent, nothing prepares you for the fear and helplessness of realizing that something meant to nourish and protect your baby would instead cause them harm. This experience shattered our sense of safety at one of the most vulnerable moments in our lives, when our only focus should have been our child's healthy growth and development.

Like many families, we chose ByHeart because of the trust it cultivated—positioning itself as a transparent, science-backed, and parent-first brand. We relied on this formula as our baby's primary source of nutrition, believing it met the highest safety and quality standards; that trust was not given lightly. We depend on companies and regulators to ensure that what reaches store shelves is unquestionably safe. When that trust is broken, the consequences are not just emotional—they were physical and long-lasting.

This crisis underscores the urgent need for stronger oversight and a faster, more proactive FDA response to contamination risks in infant formula production. We urge Congress to ensure the FDA is empowered with the resources, authority, and accountability measures necessary to prevent failures like this from happening again. No parent should ever have to question whether feeding their baby could put their child's life at risk."

Baby 5 — *in the parents' words*



"This experience has changed our lives.

From feeling disgusted in myself when I eat; seeing that my son cannot enjoy a meal with me, and from having to be his life support and watch him relearn communication; I'm convinced at times that I am incompetent.

My son's strength gives me motivation to fight and speak up for him.

I never thought being so proud to be a mother; would come with my baby meeting fear at a defenseless age.

I have faith in all who goal to correct this situation.

No matter the mountain I'm going to climb it for my son, and I appreciate you for hearing our voices."

Baby 6 — *in the parents' words*



"We want to share our experience and the profound mental and emotional hardship our family has endured following our two-month-old infant's diagnosis with botulism. This experience has been deeply traumatic, and it has permanently altered what should have been a time of bonding, joy, and learning to care for our first child. We are grateful that this situation is now being thoroughly investigated and given the serious attention it deserves, so that stronger safety measures can be put in place to prevent other families from enduring the same ordeal.

It is devastating when new parents—already navigating the vulnerability and uncertainty of caring for a newborn—are forced to confront a life-threatening illness that was both unnecessary and preventable. From the earliest weeks, we knew something was wrong. For several weeks prior to her diagnosis, we repeatedly sought medical guidance to address significant feeding challenges. More than half of each bottle would drain from her mouth, leaving us fearful that she was not receiving the nutrition she desperately needed. In response, we fed her nearly twice the recommended amount, increased the frequency of feedings, and woke her throughout the night to ensure she was getting enough nourishment.

Despite our constant vigilance and growing concern, we had no explanation for her worsening condition. Watching our newborn slowly deteriorate—without answers—was emotionally unbearable. The fear, self-doubt, and helplessness we experienced during this time are difficult to put into words. It was not until we received an automated call from the retailer where we purchased ByHeart infant

formula that we finally began to understand the cause of what our child was suffering.

Seeing our two-month-old baby connected to feeding tubes and vital monitors was one of the most heartbreaking and traumatizing moments of our lives. The emotional toll of witnessing her in that state, combined with extreme sleep deprivation, overwhelming stress, lost work, and ongoing medical and recovery appointments, has had a lasting impact on our mental health and our family's well-being.

We sincerely hope no other family ever has to experience this kind of fear and trauma during what should be the most precious and formative time of their child's life. We are thankful that this incident is receiving the attention necessary to address and correct critical safety testing deficiencies, and we pray that meaningful changes are made to ensure the safety of infants and peace of mind for parents everywhere."

Baby 7 — *in the parents' words*



"Our son was hospitalized with infant botulism after consuming powdered infant formula—something we gave him believing it was safe and carefully regulated. In a matter of days, a healthy baby lost the ability to eat, move, and function normally. No parent should ever have to watch their child suffer this way from a product specifically designed for infants. This should not have happened, and the fact that it did points to serious failures that must be addressed.

What is often missing from policy discussions is the human reality behind these cases. We are not data points or rare anomalies—we are families whose lives have been permanently altered. The emotional trauma, financial strain, and long-term uncertainty do not end when a hospital stay ends. Action is urgent because babies are still being born, parents are still relying on these products, and families should not have to wait for another child to be harmed before safeguards are strengthened. Accountability and meaningful change are necessary to ensure infant safety is truly non-negotiable."

Baby 8 — *in the parents' words*



"We believe companies can correct mistakes only when there is real accountability. In this case, warnings about potential contamination were ignored, and infant safety failed. If there isn't real regulatory change that comes from this, the message to the industry will be that the risk to babies' lives can simply be priced in as a cost of doing

business. We're asking Congress to put child safety ahead of profit and ensure this never happens again."

Baby 9 — *in the parents' words*



"I want to be able to share my perspective and take as my daughter's mom, since she is unable to advocate for herself as she is only 9 months old. She was 6 months old when she was treated for Infant Botulism at Rady's Children Hospital in San Diego CA. As a working mom, and someone who was struggling to produce milk to feed my daughter, I trusted and used the Byheart formula for only 5 weeks. It is crazy how those 5 weeks were so impactful on our daughter, and how I saw the light and spirit of her change. I had no idea what was happening to her, only knowing something was not right, as my daughter who was always a happy, outgoing, smiley baby with no health issues, was fading and changing that last two weeks before we were aware that our daughter was impacted and needed treatment for Infant Botulism.

As parents, this experience has been absolutely heartbreaking and something we will carry with us forever. We have always been extremely cautious about what we put in her body and what we expose her to from the food she eats to the clothing she wears and the toys she plays with. We carefully research products and make decisions with her safety and well-being at the forefront. We truly believed we were making the best possible choice for our child when we purchased what we thought was a high-quality, safe, and trustworthy formula. It is devastating to know that what we believed was the best choice for her turned out to be anything but.

During her illness, we watched our daughter change in ways that were terrifying and deeply distressing. Her face became frozen, her expression disappeared, and tears would roll down her face while she was unable to cry out for help, her body was weak, and she wasn't being active and strong like she normally was. At the time, we did not fully understand that paralysis was slowly spreading through her body. Not knowing what was happening, how much she was suffering, or how far the paralysis might progress is something no parent should ever experience. As a school psychologist, I worry what this impact may have on her long term social emotional well-being.

She lost abilities she had already developed — her ability to vocalize, to cry, and to control her muscles. She could not communicate her needs or discomfort, and as her parents, we were left helpless, watching our child struggle without being able to comfort her or

understand what she was feeling. We now know that had she not received medical care when she did, we could have lost our child. Even with treatment, the risk of severe and lasting long-term impacts was very real.

After treatment, her recovery was not immediate. It took significant time for her mouth and feeding abilities to improve, and while there has been progress, we continue to live with uncertainty about the long-term effects. She now struggles with ongoing gastrointestinal issues and severe constipation that requires daily medication. Because she is still so young, she cannot tell us what she feels, if she is uncomfortable, or if something is wrong, and that uncertainty is incredibly painful as a parent.

This experience has changed our family forever. The fear, the helplessness, and the lasting uncertainty are things no family should have to endure. Our hope in sharing her story is that no other child or family has to go through this. If changes can be made to prevent this from happening again, then sharing our pain and experience may help protect other children and families from enduring the same trauma."

Baby 10 — *in the parents' words*



"I researched the ByHeart formula after being told I needed to start supplementing my baby's feeds due to him losing weight. I initially chose ByHeart due to it being labeled as organic, whole milk from grass-fed cows, close to breast milk, being awarded the Clean Label Project Purity award, made by us in the US with globally-sourced ingredients, and being clinically tested. I started feeding my baby ByHeart formula on September 18th of 2025. My baby first started to show signs of Infant Botulism on October 19th of 2025, while we were attending church. He began to be unable to support his neck and started to have a decrease in his appetite.

My baby's symptoms started to increase while in the middle of moving from Washington state to Tennessee. When we arrived in Idaho Falls on October 22nd, the symptoms reached their most concerning levels. My baby was unable to lift his head and limbs, was extremely lethargic, unable to open his eyes, not crying, refusing to eat, and could not close his mouth. He was rushed to the Mountain View Hospital emergency room around 8 pm. He was admitted to Mountain View Hospital, where he stayed from October 22nd to 24th of 2025. During his stay, he was put on a feeding tube along with oxygen. On the 24th of October, the doctors consulted Intermountain Health Primary Children's Hospital in Salt Lake City, Utah, where it

was discussed that Infant Botulism was an extreme possibility, and it was decided to have him medivac'd via plane to Salt Lake City.

My baby received BabyBIG on October 25th while still in the PICU. He received treatment even though, at the time, he was not diagnosed with Infant Botulism due to his symptoms being so concerning to hospital staff. My baby was then moved from the PICU to the long-term care unit on the 27th of October. Once moved, we contacted and were approved by the Ronald McDonald organization for long-term housing due to the cost of staying in hotels for an extensive amount of time. During the entire time of our stay in Salt Lake City, we also had to pay for the boarding of our family dog.

My baby had to receive physical therapy to be able to return to bottle feeding. During this time and to this day, he has a weakness in his ability to lift and control his neck and head. My baby struggles to roll over from "tummy time" to back. My baby is not able to sit up on his own and is barely able to with assistance. Having Infant Botulism has delayed my baby's developmental progress. My baby's attitude and personality has changed significantly. My baby now becomes easily frustrated and enraged with the simple milestones that he should be hitting for his age.

This whole experience was an emotional rollercoaster due to it taking 17 months and fertility treatment to conceive. Some days, we were told that my baby could have died. Other days, we were waiting for him to get better. This has resulted in me becoming overprotective with my baby and not wanting to leave the house due to fear of my baby getting sick again. My baby, my fiancé, and I experience sleep issues due to remaining stress from this experience."

Baby 11 — *in the parents' words*



"When my daughter was sick with botulism, I felt constant, overwhelming terror. In the 7 months between her illness and the recall, I blamed myself for what happened. Since hearing of the recall, I have been anxiously fighting for answers but feeling powerless. My daughter is 1 of the 48 infants impacted by this outbreak but she is not just a number. She is a sweet, playful, strong little person who survived a harrowing experience."

Baby 12 — *in the parents' words*



"There is nothing more heartbreaking than seeing your 2-month-old baby lying in a hospital bed, covered in monitor wires and connected to IVs. Yet that became our reality.

Our son had been a healthy, happy baby. Then, suddenly, something changed. He could no longer hold his head up the way he had before. His feedings decreased, and every feeding became a struggle. We knew in our hearts that something was terribly wrong, but nothing can prepare you for the fear of watching your infant decline before your eyes.

We are extremely fortunate that we live near the Children's Hospital of Philadelphia, where the doctors and staff recognized what was happening, knew how to care for our son, and were able to obtain the BabyBIG treatment he needed. I cannot begin to imagine how much worse his condition could have become if we had not had access to that level of care.

While our son was in the hospital, and even after he was discharged, we continued feeding him Nara Organics formula. This was a formula we had researched extensively. We trusted the company's representations about its ingredients, certifications, and testing. Like any parents, we believed we were giving our baby something safe — something that would nourish him, help him grow, and support his health.

To later learn that the very formula we were feeding our son — the product we trusted to help sustain him, may have been the thing poisoning him was devastating beyond words.

No baby should ever become a victim of infant botulism from the formula they consume. No parent should have to endure the terror of watching their infant weaken, the trauma of a weeks-long hospital stay, countless tests, emotional distress, and overwhelming medical bills. No sibling should have to ask whether their baby brother or sister is going to get better, or when they will finally come home.

This is not just about our family. This is about every family who places their trust in infant formula companies and assumes that the products on store shelves have been held to the highest possible safety standards.

In the past year, there have been two infant formula-related botulism outbreaks. That should alarm every parent, every lawmaker, and every person responsible for protecting the health and safety of children. What we have learned through this experience is that

without stronger safeguards, this is not a question of if another baby will be harmed — it is a question of when.

By passing the Infant Formula Safety Modernization Act, Congress has the opportunity to help ensure that no other family has to experience what ours did. This bill can help protect the most vulnerable among us: newborns and infants who depend entirely on adults, regulators, and manufacturers to keep their food safe.

When reviewing this bill, I ask you to think not only as lawmakers, but as parents, grandparents, aunts, uncles, and members of families who love children. Imagine your own future grandchildren, nieces, nephews, or loved ones depending on infant formula for nourishment. Imagine the peace of mind that would come from knowing stronger safety measures are in place to protect them.

Our family cannot undo what happened to our son. But Congress can act to help prevent it from happening to another child.

I respectfully urge you to support and pass the Infant Formula Safety Modernization Act."

Baby 13 — *in the parents' words*



"Faced with countless infant formula options for our newborn twins, we carefully researched what we believed to be one of the safest and highest-quality ones available - ByHeart. In May 2025, at just one month old, one of them contracted Infant Botulism. Watchful waiting as your newborn becomes more limp each day and undergoes constant medical testing is a trauma no parent should ever have to endure. She spent two weeks hospitalized and her entire first year of life attending numerous Doctors appointments. This experience not only took a significant physical, emotional and financial toll on our family, but deprived us of irreplaceable time bonding with our other daughter. No parent should have to question whether the formula they trust to nourish their baby is safe; This must be treated as an urgent public health priority."

Baby 14 — *in the parents' words*



"In the early weeks of our son's life, we primarily breastfed but supplemented with infant formula out of necessity. After hours of research, we chose ByHeart infant formula based on the Organic ingredients and the claim that it was 'the closest thing to breastmilk'. We trusted that the formula we purchased had been rigorously tested and was safe for consumption. That trust was shattered when our 7-week-old became critically ill with infant botulism in October 2025.

The following weeks were spent in the hospital watching our precious boy fight for survival while being fed through an NG tube and once stable, moved to a Rehabilitation Hospital to work with therapists while he re-learned how to suck, swallow, and lift his head. Weeks that should have been spent at home bonding as a family were spent in fear and uncertainty, separated from each other and from our baby at times while he received the care he desperately needed and we took turns staying with him at the hospital. The toll that this experience has taken on our family has been enormous and we are still unpacking it months later.

The one thing that we are certain of is that stronger regulatory oversight and accountability within the infant formula industry is urgently needed to prevent other families from living the nightmare that we did."

3. Letter to this Committee of
August 28, 2026

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August 28, 2026

The Honorable Brett Guthrie, Chairman
The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Re: H.R. 7867 — the government confirmed on August 27, 2026 that the two infant botulism outbreaks were one contamination, and the bill that would have reached it is still sitting before this Committee

Dear Chairman Guthrie, Ranking Member Pallone, and Members of the Committee:

I wrote to you on June 23, 2026 in support of H.R. 7867, the Infant Formula Safety Modernization Act of 2026, and attached the statements and photographs of fourteen families whose infants were paralyzed by botulism in contaminated powdered formula.[1] I have had no reply. I am writing again because yesterday the federal government confirmed the central factual claim of that letter, and confirmed it with a laboratory result rather than an inference.

What the government confirmed 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 between April 20 and May 31, 2026. All four were hospitalized. CDC 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.

Then the finding that should bring this bill back to your markup calendar. Whole genome sequencing linked a patient sample from the Nara outbreak to a patient sample, product samples

[1] William D. Marler, *Support for H.R. 7867, the Infant Formula Safety Modernization Act of 2026* (June 23, 2026) (letter to this Committee, with Appendix A — statements and photographs of affected ByHeart and Nara families), 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, with illness onsets April 20, May 17, May 20 and May 31, 2026.

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.

In June I told this Committee that the contamination did not strike two unrelated companies by chance, and that it traveled through one shared supply stream the system missed twice. The support for that sentence was a traceback and a trade-press report. The support for it today is the government's own genome sequencing. The same organism has been found in an infant fed one brand and in the product and the ingredient of the other. A strain does not move between two babies who never consumed the same product by accident. It moves through the thing they shared.

One qualification, which you should hear from me rather than from a witness across the table. Neither agency has determined a root cause, and FDA says it cannot yet tell whether the milk was contaminated before it was dried or during the drying process. That question decides how responsibility is divided among the brands, the milk supplier and the processor. 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.

The sequencing vindicates the specific provisions of your bill

H.R. 7867 is not a general expression of concern. It does six concrete things, and yesterday's result speaks directly to four of them.

The testing list. Federal regulation still requires finished-formula testing only for *Salmonella* and *Cronobacter* and says nothing about *Clostridium botulinum*.[5] The organism that has now been sequenced across two brands, two outbreaks and fifty-two hospitalized infants is the one organism nobody is required to look for. Section 1 of your bill names it.

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[3] CDC, *Investigation Update on Infant Botulism Outbreak, June 2026* (Aug. 27, 2026), cdc.gov (whole genome sequencing analysis linking a patient sample from the Nara Organics outbreak to a patient sample, product samples and an ingredient sample collected during the 2025 ByHeart investigation; traceback finding that the infant 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. FDA describes the match set more specifically than CDC does, reporting a match to a ByHeart clinical sample, a powdered infant formula base sample, and four samples of unopened cans of ByHeart formula.

[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; the 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.

Environmental monitoring inside the plant. A single strain persisting through this ingredient stream across two manufacturers, a national recall, a federal investigation and a formal closeout is not an incidental event. It is a resident organism. Zone 2 and Zone 3 monitoring is how a resident organism is found, and it is how it would have been found before April 2026.

Foreign manufacturers held to American standards. The Nara formula was made abroad. Its milk came from an American supplier and was dried by an American processor, and the sequencing has now tied it to an American outbreak. The route your bill anticipated is the route the organism actually took.

Notice to Congress. Your bill requires notice to Congress of confirmed positives in finished formula and of any Official Action Indicated inspection finding. Consider what Congress would have known in 2025 had that provision been law, and how much of what I am reporting to you today you would already have had.

The trace-forward failure now has a measurable cost

During the 2025 ByHeart investigation the FDA did what the playbook calls for. It ran a trace-forward and asked Organic West Milk who else it supplied, so the next brand could be found before the next baby was hurt. The customer list did not include Nara Organics, and Organic West has since told the FDA that it should have.[6] 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. As of yesterday we know at the level of the genome exactly what got through.

Fifty-two infants hospitalized across the two outbreaks, many on ventilators, each treated with BabyBIG antitoxin that the State of California prices at $69,300 a dose.[7] 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.[8] Since these outbreaks began the agency has written to industry, referred questions to international scientific bodies, and held a public meeting. That is the guidance approach, tried again, and it has now failed twice with a documented body count. The duty to test belongs in statute, where it is durable and enforceable, which is what your bill does.

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[6] 21 C.F.R. § 106.55 (microbiological testing of powdered infant formula limited to *Salmonella* and *Cronobacter*; no standard for *Clostridium botulinum*), ecfr.gov.

[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; instructing that historical associations between powdered infant formula and pathogens including *Cronobacter* spp., *Salmonella*, and *Clostridium botulinum* be considered when designing and implementing controls), fda.gov/media/166044/download.

[8] 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 this Committee, with a Subcommittee on Health legislative hearing held April 29, 2026); Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), congress.gov (reported by the Senate HELP Committee 22–0 and passed by the full Senate by unanimous consent on April 29, 2026; it amends 21 U.S.C. § 350a(e) to require one-business-day notification for the microorganisms already covered by 21 C.F.R. § 106.55(e) and does not reach *Clostridium botulinum*).

What I am asking of this Committee

First, mark up H.R. 7867 and report it favorably. The Subcommittee on Health held its legislative hearing on April 29, 2026. The next step is procedural and it is yours. In June I noted, with no small alarm, that the second outbreak arrived while this bill was already pending before you. That was two months ago. The bill is still pending, and the government has now proved that the second outbreak came through the same stream as the first.[9]

Second, hold the oversight hearing. This Committee authorizes and oversees the FDA. Bring the agency, Dairy Farmers of America, Organic West Milk, Nara Organics and ByHeart before you. 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, by what method, and how often? Who prepared the 2025 customer list, who reviewed it, and when did each company learn that the same milk had reached a second infant formula brand?

Third, put the parents at the witness table. Appendix A to my June letter is fourteen families in their own words, with their children's photographs. They are willing to do more than write. 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.

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. If the answer is that no rule is coming, that is the strongest argument for your bill that anyone could give you.

We have done this before

We turned the Jack in the Box tragedy into a rule that made hamburger safer for a generation of children. This Committee has the same window open for the food we feed newborns. The Senate passed the narrower bill in April by unanimous consent; I wrote to that Committee in June and again yesterday.[10] H.R. 7867 is the bill that names the organism, monitors the plant, and reaches manufacturers abroad. It has been before you since March. Two outbreaks, fifty-two hospitalized infants, and now a genome that ties them together say the cost of waiting is no longer hypothetical. It is arithmetic.

I would welcome the chance to answer any questions from the Committee or its staff, and to make the families available to you.

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[9] 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, CDC, *Investigation Update: Infant Botulism Outbreak* (Feb. 26, 2026), cdc.gov; four infants in the Nara Organics outbreak, CDC, supra note 11.

[10] William D. Marler, *Letter to the Committee on Health, Education, Labor, and Pensions* (June 29, 2026), Marler Blog, marlerblog.com. A follow-up letter was sent to that Committee on August 28, 2026.

Very truly yours,



William D. Marler

WDM:jd
Enclosure: Letter to this Committee of June 23, 2026, with Appendix A — statements and photographs of affected families