

CITIZEN PETITION

Submitted under 21 C.F.R. § 10.30

Date: October __, 2026

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Submitted electronically at www.regulations.gov, Docket No. FDA-2013-S-0610

Re: Citizen Petition to 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 C.F.R. § 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, and twenty-three parents of infants hospitalized with botulism after being fed powdered infant formula: twenty-one parents of infants sickened in the outbreak associated with ByHeart Whole Nutrition Infant Formula, and two parents of 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 enough for a food that is the sole source of nutrition for infants.³ On March 8, 2023, the

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 C.F.R. § 106.55(e) (*Cronobacter* spp., 30 samples of 10 g; *Salmonella* spp., 60 samples of 25 g; M value of none detected for each), <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106/subpart-B/section-106.55>.

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 3–7 (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;

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 indicates that the two outbreaks share a common source of contamination, and the organism was found in a dairy ingredient. The organism is still not on the 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 stand 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
<i>Cronobacter</i> spp. (in the rule today)	30 samples / 10 g	None detected
<i>Salmonella</i> 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

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

industry’s current voluntary pathogen testing may not be sufficient for the sole source of nutrition for infants), <https://www.fda.gov/media/89876/download>. The rule is at 79 Fed. Reg. 7934 (Feb. 10, 2014) (interim final rule), corrected, 79 Fed. Reg. 9412 (Feb. 19, 2014), and 79 Fed. Reg. 33057 (June 10, 2014) (final rule), corrected, 79 Fed. Reg. 41127 (July 15, 2014).

⁴ U.S. Food & Drug Administration, *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), <https://www.fda.gov/media/166044/download>; see also FDA, *FDA’s Actions to Respond to Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula* (hereinafter “FDA’s Actions to Respond”) (describing the 2023 letter as emphasizing that manufacturers must identify and consider all known or reasonably foreseeable biological hazards, including *Clostridium botulinum*), <https://www.fda.gov/food/outbreaks-foodborne-illness/fdas-actions-respond-clostridium-botulinum-illnesses-associated-consumption-powdered-infant-formula>.

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>.

A. ACTION REQUESTED

Petitioners request that the Commissioner of Food and Drugs amend 21 C.F.R. 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 C.F.R. § 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.

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.

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.

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 supplier verification and lot-level traceability. Amend § 106.6 to require a written supplier program under which the manufacturer verifies that each supplier of a dairy-

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/ibttp/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>.

based ingredient, and each facility that dries or otherwise processes it, has implemented and validated controls for spore-forming pathogens; 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 C.F.R. § 10.30(e)(2) and, if that response is tentative, an estimate of when a proposed rule will issue.

B. STATEMENT OF GROUNDS

1. 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 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.

2. 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 of its product on November 11, 2025, and CDC declared the outbreak over on February 26, 2026.⁸ In the outbreak associated with Nara

⁷ See *supra* note 3.

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”),

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
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

<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>; FDA’s Actions to Respond (recall expanded to all ByHeart lots on Nov. 11, 2025).

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>.

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.

3. 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. 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

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 also linked the Nara patient sample to 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.

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.

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 160 days 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.

4. 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.¹⁸ ByHeart now describes routine testing of all dairy ingredients, bulk powder and finished product, with results required as a release criterion.¹⁹ Nothing requires that company to continue, or any other company to begin.

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.²⁰ 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

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>.

¹⁸ 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.

¹⁹ 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).

²⁰ 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").

plating, yet high enough to make infants sick.²¹ Industry itself has asked FDA to establish standardized testing methods and requirements.²²

5. 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.²³ 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 lasted twenty-three months.

Testing will threaten supply. The 2022 shortage was caused by contamination at a single plant and the shutdown that followed, not by the testing that found it.²⁴ 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.²⁵ 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.²⁶ FDA has since asked the International Commission on Microbiological Specifications for Foods to revisit that recommendation, and has supported a Codex request for expert advice on this organism in powdered infant formula.²⁷ A requirement in § 106.55 takes the decision away from the individual firm and gives it to the agency.

6. 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

²¹ 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>.

²² Roundtable Report, App. A Recommendation 17.

²³ Roundtable Report, App. A Recommendations 1 and 5.

²⁴ 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>; Roundtable Report at 15.

²⁵ July 2026 Letter at 2–3 (21 C.F.R. Part 106 requires ingredient specifications, quarantine and disposition of nonconforming ingredients, and regularly scheduled audits; 21 C.F.R. Part 117 requires a hazard analysis, preventive controls and, if applicable, a supply-chain program with supplier verification).

²⁶ 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.

²⁷ 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.

formula adulterated if it is not processed in compliance with them.²⁸ 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.²⁹ 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 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.³⁰ 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.

7. 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; whatever is in the can goes into the child. BabyBIG, the only treatment for infant botulism, carries a per-patient fee of \$69,300 set by California regulation, and all four Nara infants received it.³¹ If each of the fifty-two infants was treated, that is \$3,603,600 in antitoxin alone, before intensive care, ventilation, feeding tubes, rehabilitation, recalls or plant shutdowns.

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 C.F.R. § 25.30(j), which covers the issuance of current good manufacturing practice regulations. The action requested amends a current good

²⁸ See *supra* note 1.

²⁹ 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).

³⁰ *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 C.F.R. § 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.

³¹ 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).

manufacturing practice regulation, 21 C.F.R. 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 C.F.R. § 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 certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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The Honorable Secretary of Health and Human Services

Director, Office of Critical Foods, Human Foods Program, U.S. Food and Drug Administration

Deputy Commissioner for Human Foods, 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 September 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 <i>Clostridium botulinum</i>	No. A letter.
Mar. 18, 2025	Operation Stork Speed announced, including increased testing of formula and ingredients for contaminants	No. An initiative.
Feb. 2026	Initial surveillance sampling: 48 powdered milk samples from four suppliers; two positives for <i>C. sporogenes</i> 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. 3, 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.
Today	21 C.F.R. § 106.55(e) requires finished-product testing for <i>Cronobacter</i> and <i>Salmonella</i> only	Yes, and it does not reach this organism.

Sources: FDA’s Actions to Respond; 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.

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),” 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 nineteen cosponsors including Rep. Jeff Van Drew, and referred to the Committee on Energy and Commerce. 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.

Citizen Petition of William D. Marler et al. — 21 C.F.R. § 10.30
Testing for botulinum neurotoxin-producing clostridia in powdered infant formula
October __, 2026

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

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C. Nadala et al., Detection and characterization of *Clostridium botulinum* isolated from powdered infant formula, 17 *Frontiers in Microbiology* 1800624 (2026).

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

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