CAROLYN B. MALONEY, NEW YORK
CHAIRWOMAN

ONE HUNDRED SEVENTEENTH CONGRESS

JAMES COMER, KENTUCKY
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
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https://oversight.house.gov

May 12, 2022

Mr. Chris Calamari
President, U.S. and Canada Nutrition
Abbott Nutrition
100 Abbott Park Road
Abbott Park, IL 60064

Dear Mr. Calamari:

The Committee on Oversight and Reform seeks documents and information regarding the recall of your company's infant formula products and the steps your company is taking to respond to the resulting shortage of infant formula in the United States. For several months, consumers and families have been struggling to obtain infant formula amid national shortages.[1] Since the recall of several of your company's powder infant formula products following the discovery of a serious bacterial contamination in one of your primary manufacturing plants, the national out-of-stock rate for infant formula has risen to 43%.[2] In five states, the out-of-stock-rate is greater than 50%.[3]

According to the Centers for Disease Control and Prevention, approximately three-quarters of parents use formula to feed their infants.[4] As a result of ongoing supply issues, some parents are being forced to ration food or travel for hours to obtain formula, and chain retailers are instituting purchasing limits to manage inventory.[5] Third-party online retailers are reportedly taking advantage of supply shortages by charging exorbitant prices—in some cases, as much as three times the standard price for a can of formula. For families with infants who require a

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[1] Datasembly, *Datasembly's Data Reveals 31% Out-of-Stock Rate in April 2022 for Baby Formula; Up 11% Compared to 2021* (Apr. 14, 2022) (online at https://datasembly.com/news/out-of-stock-rate-in-april-2022/).

[2] Abbott Nutrition, *Recall Notice: U.S. / Puerto Rico* (Feb. 28, 2022) (online at www.similacrecall.com/us/en/home.html); Datasembly, *Datasembly Releases Latest Numbers on Baby Formula* (May 10, 2022) (online at https://datasembly.com/news/out-of-stock-rate-in-april-2022-copy/).

[3] Datasembly, *Datasembly Releases Latest Numbers on Baby Formula* (May 10, 2022) (online at https://datasembly.com/news/out-of-stock-rate-in-april-2022-copy/).

[4] Centers for Disease Control and Prevention, *Breastfeeding Among U.S. Children Born 2011-2018, CDC National Immunization Survey* (Aug. 2, 2021) (online at www.cdc.gov/breastfeeding/data/nis_data/results.html).

[5] *Baby Formula Shortage Strains Families, Forces Stores to Ration*, Washington Post (Apr. 13, 2022) (online at www.washingtonpost.com/business/2022/04/13/baby-formula-shortage/).

specific formula due to medical conditions, allergies, or sensitivities, the shortage is even more dire—causing some families to consider going to the emergency room to feed their children.[6]

This crisis was precipitated in part by what the Food and Drug Administration (FDA) has identified as your company's failure to maintain a sanitary and operational manufacturing facility, which led to potentially deadly contamination and ultimately the nationwide recall of certain powder infant formula products, as well as the shuttering of one of your primary formula manufacturing plants.[7] Recently issued FDA inspection reports demonstrate that your company failed to maintain sanitary conditions and procedures at your Sturgis, Michigan, plant for years.[8] In fact, as early as September 2021, your company was put on notice that an incident of *Cronobacter sakazakii* infection had been traced back to infant formula produced at the Sturgis facility.[9] Even more troubling, it appears that your company may have attempted to hide these dangerous breakdowns in sanitation and cleanliness at the Sturgis site from FDA inspectors.[10]

The national formula shortage poses a threat to the health and economic security of infants and families in communities across the country—particularly those with less income who have historically experienced health inequities, including food insecurity.[11] Four companies, including yours, reportedly control nearly 90% of the U.S. market for formula manufacturing.[12] It is critical that your company take all possible steps to increase the supply of formula and prevent price gouging. Given the urgent need to address this shortage, we request written responses to the following questions, as well as a staff briefing on these topics, by May 26, 2022:

1. When did Abbott Nutrition become aware of sanitation and hygiene breakdowns at its Sturgis, Michigan plant?

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[6] *A Baby Formula Shortage Leaves Desperate Parents Searching for Food*, New York Times (May 11, 2022) (online at www.nytimes.com/2022/05/10/us/baby-formula-shortage.html).

[7] *More Abbott Baby Formula Recalled After Reports of Illnesses*, CBS News (Mar. 2, 2022) (online at www.cbsnews.com/news/baby-formula-recall-similac-abbott/); *"Please Help": A Nationwide Baby Formula Shortage Worsens*, New York Times (May 11, 2022) (online at www.nytimes.com/2022/05/08/business/baby-formula-shortage-retailers.html).

[8] *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details/).

[9] *FDA Learned of Suspected Infant Formula Illness Four Months Before Recall*, Politico (Feb. 18, 2022) (online at www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226); *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details); Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (online at www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022) (accessed May 11, 2022).

[10] *Whistleblower Warned FDA About Formula Plant Months Before Baby* Deaths, Politico (Apr. 28, 2022) (online at www.politico.com/news/2022/04/28/whistleblower-fda-baby-formula-00028569).

[11] *Id*.

[12] *Monopolies and the Baby Formula Shortage*, American Prospect (May 10, 2022) (online at https://prospect.org/blogs-and-newsletters/tap/monopolies-and-the-baby-formula-shortage/).

2. What actions, if any, did Abbott Nutrition take to address and resolve these sanitation and hygiene breakdowns, and when did Abbott Nutrition take these steps?

3. Did Abbott Nutrition develop any plans or responses to mitigate the effects of recalling its infant formula products and shuttering its Sturgis plant? Please describe any mitigation measures that have been developed.

4. What steps has Abbott Nutrition taken to increase the supply of infant formula products to meet demand, and what steps is Abbott Nutrition taking going forward?

5. What steps is Abbott Nutrition taking to lower prices, prevent price gouging, or otherwise increase consumer access to its infant formula products?

6. When does Abbott Nutrition expect to have sufficient supply to meet consumer demand?

7. Please identify any issues relating to the supply chain, availability of raw materials, and availability of labor that have affected production and distribution of Abbott Nutrition infant formula products.

In addition, please produce the following documents from January 1, 2018, to the present, to the Committee by June 2, 2022:

1. All documents and communications related to sanitary conditions, quality control, or contamination at Abbott Nutrition's Sturgis, Michigan, facility, including but not limited to inspection, audit, or risk assessment reports or analyses.

2. All documents and communications related to the February 2022 recalls of Abbott Nutrition's infant formula products, including but not limited to the discovery of suspected contamination; any related testing, inspection, or investigation; and any determinations related to contaminated infant formula.

3. All documents and communications related to the closure of Abbott Nutrition's Sturgis, Michigan, facility.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Sincerely,

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable James Comer, Ranking Member
Committee on Oversight and Reform

The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.