D. Nelson
K. Barstow
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NEW ERA
SINCE 1910

February 26, 2008

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

The Honorable John Dingell
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Mssrs. Stupak and Dingell:

This letter shall serve as our response to your letter dated February 11, 2008 ("February 11 Letter") with respect to your investigation into the potential botulism contamination involving products sold by New Era Canning Company ("Company").

1. ***How and when did New Era Canning Company first become aware that botulinum toxin might be in its products?***

RESPONSE: New Era Canning Company has not been made aware that any botulinum toxin has been identified in any of its products. The Company has only been made aware that *Clostridium botulinum* **spores** have been identified.

The initial notification to the Company of the presence of *C. botulinum* spores in our product occurred on December 20, 2007 by the FDA, Ms. Joann Givens, on a conference call with me and several other FDA personnel. To-date, no official laboratory results have been received by the Company from the FDA regarding these findings.

2. ***Where and when was the botulism contamination first detected?***

RESPONSE: On December 20, 2007, the FDA advised the Company that FDA had received results that two swollen cans of green beans from one production lot tested presumptive positive for *C. botulinum* spores. The sample had been collected from product in the Company's warehouse that had been placed "on hold" or Company "quarantine" for processing issues prior to commencement of the FDA inspection on November 26, 2007.

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3. ***When did New Era first notify, or when were they first notified by, Federal, State and local officials of the contamination?***

RESPONSE: Please see Response to Question #1 above.

4. ***Please provide a list of all products that have been recalled due to potential botulism contamination?***

RESPONSE: Please see Attachment A: "List of All Recalled Product."

5. ***Please provide the names of all companies to which New Era has shipped canned bean products in the last five years and the date on which New Era notified those companies of any suspected contamination. Please provide copies of all correspondence with those companies pertaining to suspected contamination.***

RESPONSE: A list of our Company's customers is included on Attachments B. The lists include the customers that were notified about each of the four recalls our company has issued. Attachment B3 is a list of the companies that received recalled canned beans during the past five years.

Please see Attachments B1 – B4 listed below.

6. ***Please identify and describe the source of the contamination.***

RESPONSE: New Era is dedicated to the principle of first ensuring the safety of all products that we manufacture and distribute. We have taken precautionary actions to support this commitment and have already made corrections to plant conditions observed by FDA which will improve our operation. It is our desire, with outside assistance and with additional findings once received from the FDA as requested, to determine the causes of the current problems and to take whatever additional measures are deemed necessary to further protect the public health. There is more scientific assessment work to do to properly address this specific question by the Committee.

Our internal investigations are still ongoing and, in our opinion, *no definitive conclusions* can be drawn as to the source of the *C. botulinum* spore contamination in New Era products at this time. Based on the information we had received from FDA, which began its investigation November 26, 2007 and the FDA Inspectional Observations, FD-483 that was provided on Friday, February 15, 2008, closing out the inspection, we still have ***several*** scenarios that may have contributed to the cause and source of the contamination.

In addition, we are still awaiting the official FDA Laboratory Worksheets for our technical review as well as our process authorities and other outside experts, as when compiled with the results from our ongoing investigation, the official findings will be needed to better understand and refine our thinking about the actual contamination source. For example, the actual product sample condition upon opening by FDA and the

microbiological and seam evaluation evidence is critical to help determine the most likely source of the *C. botulinum* contamination of our products.

At this time, there is ***no*** investigational evidence from either the FDA or our process authorities that there are any process deviations to our scheduled processes have been improperly handled by our Company. *We believe that the normal cooking process design and those actually delivered in our retort (cooking) systems used in production were more than adequate to destroy spores of C. botulinum. These types of spores are naturally present in our product, as they are in all canned foods, prior to retorting step.*

Because of this, we have developed a list of potential scenarios which, as indicated above, could conceivably lead to the FDA findings. We are currently working to prove or disprove each of these based on our on-going investigation. These are as follows:

A. *Post Process Recontamination (Container Leakage)*: *C. botulinum* spores are ubiquitous. They are found in the soil and can become widely and normally distributed in raw products and plant environments. Spores could have mixed-in with water collecting on container can seams exiting the retort after discharge from the retort cooler. Once contaminants are in physical contact with the seam, water could draw these contaminants in through the can seam because the containers are still forming vacuum. (Cans form vacuum because they were previously heated in the cooking process (retorted) and must be cooled with water). In addition, any direct impact of these container seams at transfer points in the production line while cans are wet could increase the opportunity for seam leakage to occur and potentially draw in spores of *C. botulinum, if present.*

    a. It is possible that environmental agents normally present in the plant such as air, soil or dust could become mixed in the cooling water during operation.

    b. FDA believes that the source of these spores may have come from our Company well water as discussed below.

    c. If spores were actually present in the FDA New Era samples, they could also have originated from sources other than well water, including can line, post-retort can transfer points, and from contaminated forced-air flow from can drying equipment.

    d. Our Company had stopped chlorinating the water used in cooling the containers in all three of its thermal processing systems for a period of time in 2007 for the Malo retort line and #10 FMC Sterilmatic line.
        i. Production records document that in the Malo retort system, chlorination practices were discontinued from January 26, 2007 until reinstatement on December 18, 2007; in the FMC #10 Sterilmatic, chlorination was discontinued from March 24, 2007 and reinstated on December 26, 2007;

ii. For the FMC #300 (approximately 15 oz, net weight per retail size can) Sterilmatic, chlorination has never been practiced.
iii. While certain levels of chlorine have been shown in the literature to reduce the number of *C. botulinum* spores in water, based upon the free measurable residual of chlorine and the contact time, chlorination is *not industry practiced or controlled at concentrations or contact time for the purpose of destruction of microbial spores in cooling water.* Chlorination is, however, an effective method to reduce the amount of vegetative cells in cooling water and will reduce the risk of post process recontamination, a practice we again intend to employ.

e. The Company had installed a new can conveyor system at the beginning of the 2007 pack season which resulted in an increase in cans jamming and being damaged because of the very tight tolerances and the subsequent adjustments needed as the conveyor system was running to bring it into proper alignment.

f. Institutional can seams were evaluated by two members of the FDA inspectional team as being "low" on tightness and theoretical overlap measurements when compared to the Company's can supplier operating specifications.

B. *C. botulinum spores in Well Water*: *C. botulinum* spores were allegedly found by FDA singly, or in combination, in samples of water from all four (4) of the firm's two-hundred (200) plus feet deep wells; as well as two (2) in-plant sampling points. Our Company did find that Well #4 had a broken line about 6-7 feet below ground leading from it to a junction with Well #3 and informed FDA. The break likely occurred earlier in 2007, with an actual date unknown. It was isolated from Well #3 and is currently shut off from use. There is speculation that soil containing *C. botulinum* spores around the break may have entered the well system and the plant water supply.

C. *Retort By-pass: C. botulinum* spores are ubiquitous as stated above. Raw vegetables are grown in soils containing spores of *C. botulinum*. The spores are capable of adhering to raw product. Pre-canning steps such as washing and blanching do not remove all the spores and some may remain when product is filled into the can. The retort (cooking) step is designed to kill all spores of *C. botulinum* present in the canned product. If a can filled with beans, hot-brined and seamed somehow misses the retort (cooking) step, the product may still contain some microorganisms within the product that are somewhat similar to that which would be present if a can seam leaked as occurs in a "post-process recontamination" scenario (see above). Compared to other scenarios presented, we do not have other indicators to suggest this occurred, however some of the microbiological results from FDA could suggest such a possibility.

a. FDA has found only a few cans of our products containing *C. botulinum* spores. They have ***not*** found any pre-formed toxin. One explanation for this may center around the temperature or chemical stimulation needed for the dormant spore to germinate or grow into an actively growing and reproducing vegetative cell which is capable of producing toxin within an environment free of oxygen (i.e. in a sealed can). Typically, there must be a chemical or heat "trigger" to help stimulate spore growth into active growing vegetative cells. While there are a number of means to induce germination, one of these most effective "triggers" to spore germination is "heat shock." Spore "heat shock" can occur in a canned food if the heat process is insufficient to destroy the spores present in the product. In the laboratory, spores of C. *botulinum* can also be "heat-shocked" to stimulate the germination of the spores into vegetative cells. This typically takes a minimum of 10 minutes at 80° C. (176° F).

b. If cans were to miss the retort (cooking) step, *C. botulinum* spores that were <u>not</u> heat shocked could be present with no vegetative cells. This was apparently seen in the product by FDA analysts. Spores, if not "heat-shocked," could have been present in two of our products where allegedly found, but may never germinate into vegetative cells and produce toxin. Again, spores do not produce toxin—only vegetative cells produce toxin.

c. The FDA Arkansas Regional Laboratory (ARL) allegedly found *C. botulinum* spores in three production lots of the Company's product that had all been packed in 603 x 700 cans ((a.k.a #10) institutional cans (approximately 6-7 lbs net weight per can). Two of the Green Bean lots and the Garbanzo lot had been placed on Company "Quality Control Hold" and "quarantined" when sampled by FDA. These lots involved green beans, coded 19H7FL, 2BH7FL, and Garbanzo Beans, coded 34F7LG.

d. These lots were placed on a physical hold because they had undergone an "Emergency Still Process" while going through the FMC #10 Continuous Cooker. Our procedure for this requires removal of a specific number of infeed cans as these are not in the retort and will not receive a retort (cook) process. While these specific products were "on hold," not all records for all still-cook lots identified that these infeed cans had been appropriately removed and destroyed. While there is no indication any of these cans were shipped from any lot of product, these types of cans could result in the FDA findings.

D. *Laboratory Contamination and/or Methods Issues:* It is possible that when evaluating samples microbiologically, contaminants could be introduced into the sample product upon opening or from transferring sample product or liquid into laboratory materials. Environmental contamination present on the worker, on can-sample external surfaces, on laboratory equipment, contaminated medias or

materials or within in the laboratory itself could be involved in such laboratory contamination. Methods or techniques employed by the microbiologist/analyst could also be flawed.

The above scenarios would also address the production lot of green beans, coded 26G7FQ and sampled by FDA where it discovered several "flat" or normal cans containing spores of *C. botulinum, however, again, no preformed toxin in the product.* FDA sub-sampled the contents of these normal-appearing cans and was able to germinate the spores in specialized laboratory enrichment growth medias after heat-shock. This enrichment method germinated the *C. botulinum* spores recovered from the original sampled product. This information was taken from an FDA-provided MS Excel spreadsheet of January 17, 2008.

Based on these results, FDA's conclusion was that every #10 can is suspect (i.e. could contain *C. botulinum* spores) because:

1. Every can seam is a suspect;
2. Even the best can seams manufactured have a potential to draw in small amounts of retort cooling water;
3. The Company has not been consistently chlorinating its retort cooling water in 2007; and
4. C. *botulinum* spores were isolated ("presumptively") by FDA (*although not to-date confirmed*) from all wells and 2 in-plant sources; therefore any can coming in contact with that cooling water could have drawn in *C. botulinum* spores, capable of germinating into vegetative cells and producing toxin.

Our Process Authority, TechniCAL, Inc. has addressed the FDA "facts" and has cautioned our Company against accepting this FDA product contamination scenario at this time. They provided this advice to us because there are still ***too many questions to be answered*** in this investigation and results from all tests have not yet been reviewed nor has the FDA laboratory data been assessed in conjunction with TechniCAL's findings.

Based on the current stage of the investigation, the above potential scenarios have been addressed as follows thus far:

A. Available FDA microbiological results:

   a. At least three other FDA labs have either reported negative results or, according to the January 17, 2008 spreadsheet, still have tests that are "still in progress," so additional information is still forthcoming;

   b. FDA's concern is finding spores in flat, normal-appearing containers, containing products which were sub-cultured after container incubation.

However, it is important to note that FDA has used special laboratory techniques to encourage the germination of these spores extracted from these flat can samples using selective enrichment media which favors the growth of vegetative cells and toxin production. ***Vegetative cells capable of producing pre-formed C. botulinum toxin have not been found in any New Era products to date.***

a. Flat institutional cans of green beans were selected by FDA Investigators in our warehouse to be sent to the FDA Arkansas Regional Laboratory (ARL) lab for analysis.
    i. Twenty-four (24) flat cans (plus two swollen cans) of green beans collected at random from a code lot 26G27FQ, of approximately 8,862 cans in our Company warehouse.
    ii. This code lot was selected for examination, again at random, from approximately 597 code lots in a total production of approximately 350,000 cases (i.e. 2,100,000 cans).
    iii. Out of these 24 cans, three (3) flat cans at random were tested and with *C. botulinum spore recovery from all three (3) cans.*

b. Mr. William R. Cole of TechniCAL, Inc., a twenty-five year veteran of the USFDA (Field Investigator, Food Specialist Investigator, Office of Regulatory Affairs National Food Expert and CFSAN Special Operations Officer/HACCP), has indicated that to randomly select twenty-four (24) flat cans out of a lot of 8,862 cans, said lot selected at random from approximately 597 total codes totaling 2, 100,000 cans; then to select three (3) of these twenty-four (24) flat cans at random, take sixteen (16) gram samples out of 2,892 grams in each can and *to get C. botulinum spore recovery from all three (3) cans is highly unlikely and statistically improbable.*

c. The Institute of Environmental Health, an independent microbiological laboratory performed analysis on the same lot as above.
    i. Six (6) flat cans, two (2) swells and six (6) "buckles" of code 26G27FQ, the same as FDA, were tested.
    ii. The results formally reported on February 21, 2008 are *all negative* for anaerobic mesophilic sporeformers in all fourteen (14) samples do not show the presence of *C. botulinum* spores, or other heat resistant sporeformers in these samples.

d. These differing results need to be further studied before a conclusion can be reached.

B. We have issues concerning FDA's interpretation of what constitutes an "acceptable" or "unacceptable" can seam. According to the FD-483, can seam evaluations were visually performed by FDA on a total of eight (8) #10 cans seams for tightness, with an additional six (6) can seams evaluated for theoretical

(calculated) overlap. According to the FDA, five (5) of eight (8) cans did not meet our firm's operating specification for tightness; five (5) of six (6) seams did not meet our firm's operating specification for theoretical (calculated) overlap.

a. Theoretical overlap is based on a rough calculation, using minimum or worst case measurements. Our processing authority, TechniCAL's seam expert, Mr. Cole, has indicated that the actual overlaps, if measured on a *seam projector,* would actually be higher. Nevertheless, the actual seam overlaps calculated by the FDA Investigators still met the minimum required by an industry standard designated as the "Hold-for-Investigation" guidelines (NFPA, 1984).

b. While FDA Investigators determined that the employees at our factory were not evaluating overlap and seam tightness measurements correctly, our employees were testing the seams as trained by our company's primary can supplier. These employees were using *average s*eam component measurements. FDA, TechniCAL, our process authority, and other metal can suppliers use *minimum* seam component measurements to calculate the theoretical overlap.

c. In addition, the FDA Investigators determined that on the five (5) can seams of the eight (8) examined for tightness that they had determined to be below operating specification, that New Era's seam analysts rated the tightness of the seams higher than that of the Investigators.

d. We do not have FDA Arkansas Regional Laboratory information on laboratory can seam evaluations to accompany microbiological results.

e. To our knowledge, none of the cans examined so far by the FDA laboratories have been shown to have defective seams relative to overlap, tightness and micro-leakage according to that recorded on the January 17, 2008 FDA MS Excel spreadsheet.

C. We, like FDA, believe the best of can seams have *the potential* to leak in small amounts of cooling water during the initial stages of cooling when the seaming compound within the can seam components forms the hermetic seal and is still somewhat fluid and the can is drawing its vacuum. No one in our canning industry can guarantee that even miniscule (e.g. one micro-liter or 0.000001 liter) amounts of retort cooling water will never be drawn into the product through the best-formed can seam. This has been known, and accepted, in the canning industry for decades. However, reality is that in actual canning production practice, this is an extremely rare event since evidence of post-process recontamination occurs infrequently and in very low numbers considering total canned food units produced.

D. The Company has also collected its own water samples, using the FDA sampling instructions for water in the Investigations Operations Manual. The company duplicated the well-water and in-plant sampling locations taken by FDA, plus added an additional sample from the 24,000 gallon water silo (which FDA did not sample).

   a. These samples are currently being analyzed by Silliker Labs in South Holland, IL, a national independent private testing laboratory.

   b. The samples were collected on February 8, 2008, placed under New Era seal and refrigeration, and delivered overnight to be received on February 9, 2008.

   c. The microbiological laboratory director, Dr. Erdogan Ceylon, has indicated the samples were received with all seals intact, attesting to the integrity of the sample.

   d. Sample testing began the week of February 12, 2008. *[Note*: We have spoken with Dr. Ceylon today and while not yet conclusive, the anaerobic mesophilic sporeformer counts in the samples provided have tested low and there is no evidence to-date of the presence of *C. botulinum* spores in our well and in-plant water samples currently under evaluation.]

   e. We expect these analytical results to be verbally relayed to our Company no later than February 28, 2008.

   f. These differing water sample results between FDA Laboratories and our private laboratory need to be further studied and resolved.

We will be happy to provide additional information when our investigation is completed.

7. ***What steps has New Era taken to prevent further botulism contamination in its products?***

RESPONSE: The Company has ceased all production in its New Era facility. Investigations are ongoing and we intend to fully comply with any requirements identified. However, our investigation is not complete and we have not yet received all the technical data complied by FDA for review by our company or our experts.

Our company had initially engaged the efforts of numerous process authorities who are represented by our suppliers [e.g. FMC FoodTech, Institute for Environmental Health (IEH), Ball Corporation, and individuals, Mr. Keith Ito and Mr. Roger Jackson] to help us investigate the issues raised during FDA's earlier weeks of investigation. Most recently, we have hired an independent process authority, TechniCAL, Inc., well respected by FDA, who has provided exclusive process authority services of two experienced individuals (Mr. William R. Cole and Mr. David K. Park). They have

helped represent our firm in technical and recall-related matters (including investigational and administrative) since January 29, 2008.

8. ***When was the last time that New Era's production facility was inspected by the U.S. Food and Drug Administration and State and local food safety officials? Please provide the dates of such inspections and the names of the officials, as well as all documents associated with those inspections and ongoing inspections.***

RESPONSE: Please see Attachment C: "List of FDA, USDA and State/Local Food Safety Inspections". This list contains all inspections of the Company's inspections for the prior 5 years. We have attached the reports from each inspection.

9. ***Please provide all records relating to such inspections of New Era's processing facility for 5 years prior to January 18, 2008.***

RESPONSE: Please see information provided for Question 8.

10. ***Please provide copies of all New Era internal protocols and standards for monitoring and testing in its food products, including the dates and copies of the results of such monitoring and testing that tested positive for microbiological contamination for 5 years prior to January 18, 2008.***

RESPONSE: New Era Canning Company does not currently conduct microbiological testing of finished product on a scheduled basis. We have enclosed examples of the production forms that are used to monitor the processes, critical factors, and overall quality of various product groups in lieu of including one for each New Era SKU. We have recently submitted samples to Ball Corporation.

Please see Attachments D1 – D4 listed below.

Sincerely,

Rick Ray
President and CEO
New Era Canning Company

Attachments to New Era Canning Company's Response to Committee on Energy and Commerce Letter Dated February 11, 2008

Attachment A:	List of all Recalled Products
Attachment B1:	List of all Companies to Whom New Era Canning Company has Shipped Recalled Canned Vegetable Product - Customers involved in Green Bean Recall of 12/21/07
Attachment B2:	List of all Companies to Whom New Era Canning Company has Shipped Recalled Canned Vegetable Product - Customers involved in Canned Vegetable Recall of 1/08/08
Attachment B3:	List of all Companies to Whom New Era Canning Company has Shipped Recalled Canned Vegetable Product in Last Five Years - Customers involved in Green Bean and Garbanzo Bean Recall of 1/18/08
Attachment B4:	List of all Companies to Whom New Era Canning Company has Shipped Recalled Canned Vegetable Product - Customers involved in Canned Vegetable Recall of 2/07/08
Attachment C:	List of FDA, USDA and State/Local Food Safety Inspections
Attachment D1:	Sample Production Forms for Green Beans Processed in the FMC Rotary Cooker
Attachment D2:	Sample Production Forms for Dark Read Kidney Beans Processed in the Malo Retorts
Attachment D3:	Quality Assurance Product Testing Program, Daily Cutting Forms and Minute-By-Minute Logs for All Products
Attachment D4:	Microbiological Evaluation of New Era Canning Spoilage by Ball Corporation