Subject: FW: Nestle Bottled Water letter
Date: Wednesday, February 7, 2024 at 4:37:22 PM Eastern Standard Time
From: Whitman, David
To: Robin, Lauren (Posnick), South, Paul, Long, Nicholas
CC: Lunzer, Jesse, Whitman, David
Attachments: image001.png

Hi Nick,

Jesse and I reviewed the letter. We appreciate Nestle providing the information. However, due to the limited information provided we are unable to assess whether the bottled water products produced by the brands are safe, or whether a recall should be initiated.

While the details of E. coli in source water and other apparent cGMP deviations are concerning, without addition information regarding the process water treatments applied at each facility, we cannot comment on the safety of the bottled water. Generally, when we have questions about a firm's regulatory compliance, we conduct a comprehensive inspection to obtain the details needed to determine if an action is required. We note that while 129.35(3)(i) states, "Source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for use in bottled water by paragraph (a)(1) of this section," the water processing steps of each facility (e.g., (b) (4)) may adequately reduce or eliminate the risk posed by *E. coli* and the products may not need to be recalled. Properly designed and operated (b) (4) treatments can be effective in that regard.

The claims of continued use of a source that has been found positive for E. coli without first taking the required corrective actions could (b) (5) . Has OC considered (b) (5) ? Happy to further discuss.

Involving (b) (5) .

Best,

David G. Whitman, Senior SME
Beverage Branch
Division of Plant Products and Beverages
FDA / CFSAN / Office of Food Safety
240-402-3754 (Pacific Time Zone)

U.S. FOOD & DRUG ADMINISTRATION

NTEU Steward Chapter 212

From: Lunzer, Jesse <Jesse.Lunzer@fda.hhs.gov>
Date: Wednesday, February 7, 2024 at 10:54 AM
To: Whitman, David <David.Whitman@fda.hhs.gov>

Subject: Re: Nestle Bottled Water letter

Seems like they're trying to get ahead of bad press. In general, we have a precedent for allowing bottled water not to be recalled although it was made with source water that tested positive for E. coli (Niagara 2019). We took the position that FSMA would allow reconditioning of the product and the extensive processing at Niagara ((b) (4)) eliminated the risk.

I'd want to review to filter and (b) (4) system details and SOPs, filter replacement/fail safes, etc.

We can discuss more later.

From: Whitman, David <David.Whitman@fda.hhs.gov>
Date: Wednesday, February 7, 2024 at 10:08 AM
To: Lunzer, Jesse <Jesse.Lunzer@fda.hhs.gov>
Subject: FW: Nestle Bottled Water letter

Please review and then we can discuss

David G. Whitman, Senior SME
Beverage Branch
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FDA U.S. FOOD & DRUG ADMINISTRATION

NTEU Steward Chapter 212

From: Robin, Lauren (Posnick) <Lauren.Robin@fda.hhs.gov>
Sent: Tuesday, February 6, 2024 7:02 PM
To: South, Paul <Paul.South@fda.hhs.gov>; Whitman, David <David.Whitman@fda.hhs.gov>
Subject: Fwd: Nestle Bottled Water letter

Hello,

I'm assuming this should go the two of you. Can you please confirm and I will let Nick know?

Thanks
Lauren

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From: Long, Nicholas <Nicholas.Long@fda.hhs.gov>
Sent: Tuesday, February 6, 2024 8:03:25 PM
To: Robin, Lauren (Posnick) <Lauren.Robin@fda.hhs.gov>
Cc: Jones, Robyn R <Robyn.Jones@fda.hhs.gov>
Subject: Nestle Bottled Water letter

Hi Lauren,

I am reaching out concerning the attached letter. This was sent to FDA (Anne Oxenham) from Nestle's counsel. A copy of the letter has been sent to (b) (5) .

We would like to ask if (b) (5) ?
This will allow us a more measured pace for the rest of the process.

If possible, we'd like to request prioritization of this review. (b) (5) so any review that can be done in that timeframe would be greatly appreciated.

We understand this is a quick timeframe, but as this potentially gets into the news it may draw a lot of attention and we want to try to address the optics/inquiries as best we can.

Please let me know if you have any questions.

Thanks

*Please note that the letter contains Trade Secrets and Confidential Commercial info

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January 29, 2024

By Electronic Mail

Ms. Anne Oxenham
Director, Office of Compliance
Center for Food Safety and Applied Nutrition
5001 Campus Dr.
College Park, MD 20740
Ann.Oxenham@fda.hhs.gov

Re: Regulatory Noncompliance Issues for Perrier, Acqua Panna, and S. Pellegrino Bottled Waters Subject to 21 CFR Part 129

Dear Ms. Oxenham:

We are writing on behalf of our client Nestlé USA, Inc. (Nestlé) to bring to the agency's attention an issue involving non-compliance with certain requirements of 21 CFR Part 129 with regard to the production of the above-referenced bottled waters which are imported from France and Italy. We are aware of a story that likely will be appearing in the French media this week about misleading practices that existed at the Perrier facility in France. While not expected to appear in news media, we understand that similar practices existed at the S. Pellegrino and Acqua Panna facilities in Italy. We wanted to bring this issue to the agency's attention in advance of any media stories that may appear in the United States. With regard to the status of products on the market, Nestlé is confident the products it has produced at these facilities are safe and do not present a health or safety issue. We are sending this letter to bring this issue to the agency's attention and to begin the dialog with the agency about the practices that are being implemented to address them.

Facility Design Issues

We anticipate the French media will be reporting a story in the near future regarding conditions that existed at the Perrier facility that allowed (b) (4) treatment of water to take place outside of the awareness of French regulatory authorities. The Perrier facility was designed with (b) (4) Similar designs exist in both the S. Pellegrino mineral water facility and the Acqua Panna spring water facility, where water that would appear to be untreated was subjected to (b) (4) prior to sampling. Samples pulled by or provided to

regulators to document compliance with raw source water requirements were represented as untreated water when the water had actually been subjected to treatment. As you may know, European regulations restrict the use of (b) (4) and other treatments that remove micro-nutrients from mineral water. Accordingly, (b) (4) .

Nestlé has been working with the French authorities on this issue since August 2021 and has implemented corrective actions that we believe the French authorities will consider appropriate to comply with the relevant requirements for natural mineral water under French and EU law. This week Nestlé will initiate contact with the Italian government and will work with those officials to implement the appropriate corrective actions for the S. Pellegrino and Acqua Panna facilities that will be required under the relevant Italian and EU requirements.

With regard to the U.S., Nestlé is providing in this letter a summary of practices that we view as falling short of the requirements in the bottled water GMPs. Nestlé also is committed to providing FDA with the corrective actions that have been or will be implemented to demonstrate compliance with the relevant U.S. requirements. We also wanted to bring to FDA's attention concerns with the information collected by FDA during its 2017 inspections of the Perrier facility and S. Pellegrino facility. Any data or information collected during FDA inspections of the Perrier, Acqua Panna, or S. Pellegrino facilities with regard to the status of the "raw source water" would have been based on previously treated water.

Source Water Testing Issues

As the agency is aware, the bottled water GMPs require source water other than water from a municipal water source to be sampled and analyzed at least once per week for coliforms and, when coliforms are detected, follow-up testing is required to determine if there is *E. coli*. 21 CFR 129.35(a)(3)(i). When the bottler finds *E. coli*, the regulation specifies the corrective actions that should be considered, such as rectifying or eliminating the cause of the *E. coli* and collecting samples that can be used to demonstrate the source is considered negative for *E. coli*. *Id.*

Over the past several years, each of the three facilities has detected *E. coli* in source water (tested prior to any treatment) but then (b) (4) Nestlé is confident the processing conducted at each facility, as verified by its finished product testing, has eliminated the potential for product to contain coliforms or *E. coli.* We provide more details below regarding the testing at the various facilities.

S. Pellegrino and Acqua Panna

The manufacturing process for S. Pellegrino and Acqua Panna begins with (b) (4) for Acqua Panna. The (b) (4) . Testing conducted over the past several years has found *E. coli* in certain samples and on certain occasions in the (b) (4) but neither coliforms nor *E. coli* have been detected in (b) (4) . In addition, the process at each facility involves (b) (4) . All finished product is tested and it is our understanding coliforms have never been found in the finished product. The finished product testing verifies the (b) (4) is an effective process

control for removing coliforms from the raw source water. This manufacturing process applies to all S. Pellegrino® and Acqua Panna® products. (Note: This discussion does not apply to the San Pellegrino® Italian sparkling drinks which are not labeled as and are not mineral or spring water products subject to 21 C.F.R. 129.35, and which also use water from a different water source, not the wells that had the positive *E. coli* detections).

Perrier

As noted earlier Perrier has been working closely with the French authorities since August 2021, including disclosing the facility design issues described above. In September 2022, Perrier ceased using any source wells that did not comply with the coliform requirements of the bottled water GMPs on the basis of test results from the raw untreated source water. For the U.S. market, Perrier continues to use (b) (4) when the water is pumped from the source. Prior to bottling, water for the U.S. market also is subjected to (b) (4) treatment system that is represented by the supplier as being compliant with U.S. requirements is used. All product produced from the U.S. market since September 2022 has been sourced from wells that test negative for *E. coli* and has been subjected to (b) (4) treatments. Nestlé is confident the Perrier product produced since September 2022 complies with the U.S. requirements. (Note Nestlé will be (b) (4) .)

Perrier products have a shelf life of 15-36 months depending on whether the product is packaged in PET (15 months), a can (18 months), or glass (36 months). We next turn to practices prior to September 2022 because we believe there are products in the market that are still within shelf life. In September 2021, an extremely large rainfall event (over 9 inches of rain in 24 hours) caused flooding in some of the (b) (4) and *E. coli* was detected in pre-treatment source water samples for (b) (4) of the wells. We understand the *E. coli* detections subsided over time and it appeared the source of the *E. coli* contamination could be attributed to the flooding event. It, nonetheless, appears Perrier (b) (4) without strictly following the provisions recommended in 21 CFR 129.35(a)(3)(i) when a source tests positive for *E. coli*. Nestlé is confident Perrier product produced prior to September 2022 is safe. The Perrier process at the time also involved the treatment of the source water with (b) (4) (b) (4) . In addition to (b) (4) Perrier also would subject the water to a (b) (4) treatment. The (b) (4) treatment would function as an appropriate process control to address the potential risk of *E. coli* in the source water. The testing of the source water after the (b) (4) and the finished product testing of the finished bottled water serves as a verification activity of this process control and the finished product testing verified the efficacy of the treatments for eliminating *E. coli.*

Safety Assessment

Nestlé is in the process of (b) (4) available to FDA when it is completed. It is the Nestlé view the products in the U.S. market do not present a health or safety issue for the reasons summarized below.

- Nestlé selected either (b) (4) developed for the food and beverage industry with accompanying validation information from the filter suppliers.
- Nestlé has appropriate protocols for monitoring performance and maintaining the (b) (4). It pulls (b) (4)). When Nestlé sees (b) (4) . The constant monitoring of (b) (4) levels provides a means to verify the proper functioning of the (b) (4) .
- Each system involved (b) (4) . All finished product would have been subjected to (b) (4) . The (b) (4) .
- The bacterial pathogens of concern such as *E. coli* have a size that is (b) (4) (b) (4) used in the process. The size of the *E. coli* and the other bacteria of potential concern should (b) (4) .

- For Perrier, all product shipped to the U.S. also received treatment with (b) (4) to provide further support that any *E. coli* in source water would be eliminated by the process.
- Testing of the (b) (4) source water verifies the (b) (4) effectively removes the coliforms and *E. coli* from the source water.
    - Nestlé used the following sampling program to test the treated source water. For Acqua Panna the establishment would collect (b) (4) . For S. Pellegrino and Perrier the establishment would collect (b) (4) . The establishment would test (b) (4) of the sample for each well for coliforms and *E. coli.*
    - All results across all three facilities consistently showed the (b) (4) removed coliforms. The establishments report that they never found coliforms or *E. coli* in the source water that had been subjected to (b) (4) . The absence of any

positive *E. coli* or coliform in the (b) (4) water provides compelling verification for the ability of the (b) (4) to remove coliforms and *E. coli*.

- Finished product testing provides a further verification activity.
    - Nestlé tests each production lot to ensure the water meets relevant specifications for purity and quality. Finished product samples are collected for each purchase order for Perrier and for each production lot for Acqua Panna and S. Pellegrino. Samples of finished products are pulled that will result in (b) (4) of product for testing. A (b) (4) sample is tested for *E. coli* and coliforms.
    - Finished product testing has never identified *E. coli* in the finished product providing a verification activity for the process control.

While Nestlé is confident it has controlled the hazard of potential contamination with *E. coli* we also wanted to bring to the agency's attention additional information in the Nestlé files. Nestlé does not have records of the cleaning or maintenance of the (b) (4) systems at Acqua Panna, S. Pellegrino, or Perrier prior to September 2022 because it conducted these activities outside of the bottled water GMPs and its food safety plan. While Nestlé is confident the (b) (4) will remove *E. coli* and coliforms and each supplier has provided validation information, Nestlé has not conducted a study that specifically evaluates the use of the (b) (4) in its system. We also wanted to bring to FDA's attention testing conducted by Nestlé for purposes of the EU market. The EU has a prohibition on disinfecting mineral water. To satisfy the EU requirements that (b) (4) does not disinfect the mineral water, Nestlé has collected data demonstrating detectable levels of microflora can be found in the final product (i.e., water that has gone through (b) (4) processes). Again, Nestlé is confident the filtration system has been effective in removing any potential *E. coli* from the source water, but in the interest of disclosure, we wanted to make certain we shared this information with the agency.

Nestlé has spent decades building its reputation as a company that is committed to food safety. Nestlé takes seriously the nature of the issues in this letter, is taking responsibility for failing to meet its responsibilities for regulatory compliance, and is putting the controls in place to make certain these type of issues cannot happen again.

We recognize the agency will need time to review and consider the information in this letter. Please also recognize we have had limited time to pull together the information in this letter. Nestlé remains committed to full cooperation with FDA and is conducting a complete and thorough investigation. To the extent we discover additional information in the future that would be of assistance in the agency's assessment, Nestlé is committed to sharing that information with the agency in a timely manner.

Please let us know if the agency would like to arrange a call to discuss or if the agency has any requests for additional information.

Sincerely,

Martin J. Hahn

Partner
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