

May 29, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515-6115

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515-6115

Dear Chairman Dingell and Chairman Stupak:

On May 22, 2008, we provided a partial response on behalf of our client, The Coca-Cola Company ("the Company"), to your May 8, 2008 letter to its Chairman and CEO, E. Neville Isdell.

Some brief background will help put this round of the Company's response in context. As you would expect, the Company performs an enormous amount of testing related to its ingredients and products. The bulk of this testing occurs at the earliest stages of ingredient sourcing and is designed to assure the food safety and quality of the Company's concentrates, beverage bases, food service syrups, and finished products by building quality and integrity into the Company's ingredient sourcing and manufacturing processes. To this end, the Company has developed (1) demanding and comprehensive ingredient specifications and (2) rigorous practices designed to ensure that ingredient suppliers consistently deliver ingredients that meet those specifications. For example, the

Company has established qualification standards and criteria that every supplier must meet before even being considered to be used as a supplier.¹ Moreover, the Company routinely audits its suppliers and subjects them to periodic review. Simply put, the Company retains only those suppliers that meet -- and continue to meet -- the Company's high expectations.

The Company requires that every non-juice ingredient shipment must be accompanied by a comprehensive Certificate of Analysis confirming that the Company's specifications have been tested for and met. Additionally, the Company may test incoming ingredients upon receipt to confirm key elements of the specifications. Moreover, the Company will often require pre-shipment product samples and will subject the samples to quality and safety testing. As a result, ingredients that fail these early tests are never even shipped to the Company for possible use. The Company also tests trade and production samples of finished products for a number of attributes, primarily those related to quality.

In addition, the Company produces juice products in a manner consistent with FDA's juice HACCP regulations, 21 CFR Part 120. These regulations mandate that juice processors have in place programs that identify, address, and monitor the potential for physical, chemical, and microbiological hazards to occur. The Company requires all juice suppliers to comply with the HACCP regulations. Juice products produced by the Company are then processed in accordance with the HACCP requirement that the process be capable of delivering a 5 log reduction in any potential pathogenic organisms.

The Company produces its bottled water in a manner consistent with FDA's standards of quality for such products (21 CFR Part 165) and the agency's mandatory cGMP (current good manufacturing practices) regulations (21 CFR Part 129). These requirements, the latter in particular, are designed to ensure not only the integrity of the products themselves but also that the source water to be bottled is from an approved source that is in compliance at all times with applicable laws and regulations of every governmental agency having jurisdiction.

In every case, the upshot of these practices is the production of products of consistent quality and integrity. Only on rare occasions has a question of regulatory compliance attended a Company product. When such questions arise, the Company responds in the currency you would expect: scientific investigation, the collection of dispositive data and information and, where appropriate, product recall (as noted in our May 22 response to Question 1 of your letter).

¹ We have attached (Attachment A) the Company's 28 page Supplier Expectations Brochure which describes, in general, the Company's standards and criteria.

With the foregoing as general context, the Company's responses to your questions follow.

Question 2: For each brand or kind of product, please list all instances when internal microbiological testing was found to be positive for the presence of *E. coli*, *Salmonella*, *Cyclospora cayetanensis*, *Cryptosporidium*, hepatitis A, *Clostridium botulium*, or *Listeria* in excess for the highest limit acceptable to the Food and Drug Administration (FDA) or any State regulatory authority.

Response: No instances.²

Question 3: For each brand or kind of product, please list the instances when internal testing was found to be positive for the presence of a chemical contaminant at levels in excess at the highest limit acceptable to FDA or any State regulatory authority.

Response: The Company's electronic records reveal two isolated instances where test results indicated a data point marginally above (2ppb) an FDA bottled water acceptable limit. See Attachment B.³

² With respect to microbiological contamination of the types identified in your May 8 letter, the International Commission on Microbiological Specifications for Foods, an internationally recognized authority on food safety has observed that:

No significant microbiological [health] hazards are associated with [carbonated and non carbonated] soft drinks because of the product and processing methods used for production.

(ICMSF, 2005. *Microorganisms in Foods. 6. Microbiological Ecology of Food Commodities*, 2nd ed. Kluwer Academic/Plenum Publishers, New York, NY.P. 565). With respect to juice products, the Commission endorses the beneficial effects of control measures like the 5-log reduction required by FDA.

³ We note that in responding to your letter, we have not considered issues involving California's ballot initiative, Proposition 65, and substance levels that simply trigger the general warning provisions of that initiative and nothing else. Levels that represent a Proposition 65 warning threshold do not constitute the highest level acceptable to a State regulatory authority. In fact, by definition, California allows contaminants in excess of these levels but requires that consumers be informed about their presence (unless the contaminants are naturally occurring).

We also note that survey data collected by FDA revealed in 2006 the presence of benzene at levels, with few exceptions, below 5ppb in soft drinks produced by the nation's soft drink manufacturers. FDA has never established a regulatory limit for the presence of benzene in beverages and has concluded that the levels of benzene found in survey data like those reported

Question 4: For products imported into the United States for handling or processing by any facility operated by your firm, please list the instances when internal or outside laboratory testing was positive for the presence of either a chemical or microbiological contaminant in excess of FDA or State regulatory limits.

Response: From January 1, 2003, through May 15, 2008, the Company conducted or caused to be conducted testing on over 20,000 samples of imported or proposed to be imported juices and other ingredients.⁴ In sixty-two samples of the imported juice, a non-compliant contaminant was identified (18 of these instances involved pre-shipment lots that were neither purchased nor imported). As the attached list (Attachment D) reveals, 48 of the samples were found to contain the presence of a pesticide not allowed on the relevant fruit type, 7 involved a contaminant with no known tolerance, and 7 identified levels of Patulin (a mycotoxin produced by a variety of molds) exceeding FDA's defect action levels. The Company rejected all the lots of product to which the non-compliant results applied. No product was manufactured from such lots.

Question 5: For each of the above items, please specify whether FDA was notified, and if not, why not.

Response: With respect to the two isolated cases noted in the Company's response to Question 3, FDA was not notified; the reasons are provided in Attachment B. Nor was FDA notified in the cases noted in the response to Question 4 for the obvious reason that each case involved the rejection of an ingredient *before* it was used in the manufacture of a product.

Question 6: Please supply a list of all instances where FDA or any State regulatory authority was denied entrance to any facility, foreign or domestic, or denied access to any records regarding microbiological or chemical testing performed on products processed at the facility. This request encompasses denials of initial requests for entry or any such testing record regardless of whether the plant or its records were to be made available for inspection at a later date.

in 2006 do not pose a safety concern for consumers. Naturally, as you would expect, the Company has undertaken initiatives to minimize the level and the frequency of occurrence, including product reformulation. We have attached a press release announcing a legal settlement involving the Company in a consumer-based lawsuit against the Company arising from consumer concern. *See* Attachment C.

⁴ The majority of the Company's testing is performed in-house. When the Company resorts to "outside" testing laboratories, it employs only those laboratories it has authorized and audited.

Chairman Dingell and Chairman Stupak

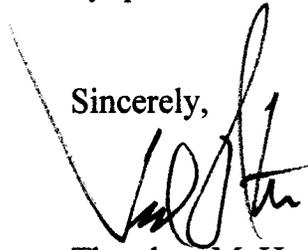
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Response: The Company is not aware of any instance where FDA, an FDA Investigator, or a comparable State regulatory authority or official has been denied access to a Company-owned facility. As you are aware, however, Section 704 of the Food, Drug, and Cosmetic Act does not provide FDA with the authority of general access to most records, including records reflecting test data, in facility or company files. The Company's formal written policy on inspections provides that if FDA or a comparable regulatory authority requests access to any such records, the Company official receiving the request is instructed to consult with the Company's Quality Department in Atlanta with respect to the matter. The Company is unaware of any instance where it has responded in a manner that failed to address the questions or concerns of the regulatory authority or official.

Should this correspondence raise any question or concern, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Theodore M. Hester', written over the word 'Sincerely,'.

Theodore M. Hester

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigation