Juicer Connections, LLC. 9/21/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
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WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

September 21, 2016

WL #48-16

Steven A. Mullen, Owner
Juicer Connections, Inc.
1920 Mc Garry Street
Los Angeles, CA, 90058-1030

Dear Mr. Mullen:

During an inspection of your firm located in Los Angeles, CA on April 11, 2016 through May 2, 2016, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures juice products. During this inspection, our investigators found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and its implementing regulations at **www.fda.gov (http://www.fda.gov/)**.

JUICE HACCP

FDA's inspection from April 11, 2016 through May 2, 2016 also revealed serious deviations from the FDA's juice Hazard Analysis and Critical Control Point (HACCP) regulation in Title 21, Code of Federal Regulations, Part 120 (21 CFR 120). The inspection resulted in FDA's issuance of a Form FDA-483, Inspectional Observations (FDA-483), at the conclusion of the inspection which listed the deviations found at your firm.

In accordance with 21 CFR 120.9, failure of a processor to have and implement a HACCP plan that complies with the requirements of Part 120, renders the juice products adulterated within the meaning of Section 402(a)(4) of the

Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(a)(4)]. Accordingly, your 100% juice products are adulterated in that they have been prepared, packed, or held under conditions whereby they may have been rendered injurious to health. You may find the Act, the juice HACCP regulation, and the Juice HACCP Hazards and Controls Guidance through links in FDA's home page at:
http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm (http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm).

FDA acknowledges your written response to the FDA-483 dated June 3, 2016. Your response included newly created HACCP plans, product formulations, a Sanitation Standard Operation Procedures (SSOP) document, and blank monitoring records. After reviewing your response, we continue to have concerns with the following significant deviation:

You must include in your hazard analysis and HACCP plan control measures that will consistently produce, at a minimum, a 5-log reduction of the pertinent microorganism for at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, to comply with 21 CFR 120.24(a). Your juice process now includes the **(b)(4)** of a wide variety of juices (as opposed to your previous **(b)(4)** process) as your 5-log reduction pathogen reduction step. However, your firm has not validated, as required by 21 CFR 120.11(b), that the **(b)(4)** achieves a minimum 5-log reduction of the most pertinent organism for your 100% juice products.

Your 483 response, dated June 3, 2016, indicates you have begun validating your **(b)(4)** process for all of your juice products and validation will be completed "in the next couple of weeks." However, as of the date of this letter, you have not provided any documentation of your ongoing validation efforts and/or the results of such process validations. Please respond with a timeline of completion for process validations for each of your juice types. In addition, FDA is not aware of any broad **(b)(4)** validation study that covers juice products with varying compositions, characteristics, pertinent microorganisms, etc. Processors subject to the juice HACCP regulation (21 CFR 120) are required to validate **(b)(4)** processes for each type of juice products they process. If a processor works with a process authority and provides data to demonstrate that a **(b)(4)** validation study can be applied to several juice products grouped together, FDA would need to evaluate the validity of the data on a case-by-case basis.

In addition, your response indicates that your validation efforts will ensure the 5-log reduction in pathogens "such as *E. coli, Salmonella*, and *L. monocytogenes* in acidic and low acid fruit, vegetable, or blended fruit and/or vegetable juices." Although your response indicates you will acidify all juices prior **(b)(4)** processing, any validation involving low-acid juices, not acidified below pH 4.6, should identify *Clostridium botulinum* as the pertinent microorganism. Currently, the FDA does not consider **(b)(4)** a validated process that can eliminate the spores of *Clostridium botulinum* in low-acid juices. For this reason, it is critical that your firm adequately control pH in products containing low-acid juices that you intend to acidify. For further information related to microbiological concerns in low acid juice products, please reference this FDA guidance document:
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072481.ht (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072481.h
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UNAPPROVED NEW DRUGS

In addition, FDA reviewed your product label for your **(b)(4)** product following the inspection of your facility. The claims on your product label establish that the product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B)] because it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for introduction into interstate commerce for such uses violates the Act.

Examples of some of the claims on your product label that provide evidence that your product is intended for use as a drug include:

"People who drank juices (fruit and vegetable) more than three times per week were 76 percent less likely to develop Alzheimer's disease, according to the Kane Project 1."

Your product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your product **(b)(4)** is intended for prevention of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for its intended purposes. Accordingly, your **(b)(4)** product fails to bear adequate directions for its intended use and, therefore, the product is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of this misbranded drug violates section 301(a) of the Act [21 U.S.C. 331(a)].

MISBRANDING

1. The Juice Connection Lemon Juice, Lime Juice, Grapefruit Juice, Watermelon Juice, and Orange Juice products and the **(b)(4)** product are misbranded within the meaning of section 21 U.S.C. §343(e)(2) [403(e)(2) of the Act] because the product labels fail to declare the net quantity of contents on the principal display panel as required by 21 CFR 101.105.

2. Your Juice Connection Lemon Juice, Grapefruit Juice, Watermelon Juice, Orange Juice, and the **(b)(4)** products are misbranded within the meaning of section 21 U.S.C. §343(i)(2) [403(i)(2) of the Act] in that they purport to be beverages containing vegetable or fruit juice but fail to bear a statement with appropriate prominence on the information panel (for packages with information panels) of the total percentage of such fruit or vegetable juice contained in the food as required by 21 CFR 101.30.

Your Juice Connection Grapefruit Juice product is misbranded within the meaning of section 21 U.S.C. § 343(a)(1) [403(a)(1) of the Act] in that the labels are false and misleading in any particular. Specifically, the use of the term "fresh" on the label of the Juice Connection Grapefruit Juice product to describe the grapefruit juice in the ingredient list is inconsistent with the definition of "fresh" in 21 CFR 101.95(a). Under 21 CFR 101.95, the term "fresh," when used on the label or in the labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation. According to your firm's ingredient list and based on the observation of our investigators, this product is made from grapefruit juice concentrate. Therefore, the product is not in its raw state and may not be characterized as "fresh."

3. The Juice Connection Orange Juice, Lemon Juice, and Grapefruit Juice products are misbranded within meaning of section 21 U.S.C. § 343(g) [403(g) of the Act]. The products appear to be represented as foods for which a

definition and standard of identity have been prescribed by regulations as provided by section 401 and the foods do not appear to conform to such definition and standard in accordance with 21 CFR 146.135, 146.114, 146.132. Specifically,

- The Orange Juice product is made with reconstituted orange juice; however, Orange juice is a standardized food and does not provide for reconstituted orange juice. [21 CFR 146.135]
- The Lemon Juice and Grapefruit Juice products are made from concentrate; but the names of the food fail to indicate that fact. [21 CFR 146.114, 146.132]

4. Your Juice Connection Watermelon Juice and **(b)(4)** products are misbranded within the meaning of section 21 U.S.C. § 343(i)(1) [403(i)(1) of the Act] because the product labels fail to bear an appropriate statement of identity as required by 21 CFR 101.3. Specifically,

- Under 21 CFR 102.33(a), for a carbonated or noncarbonated beverage that contains less than 100 percent or more than 0 percent fruit or vegetable juice, the common or usual name must include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice if the common or usual name uses the work "juice." Our investigator observed the production of the Watermelon Juice product using 35 gallons of expressed watermelon juice, 15 gallons of water, and 12.5 tbsp. of citric acid. Therefore, due to the addition of water, the product is not 100% juice. Under 21 CFR 102.33(a), this product cannot be named using the word "juice" unqualified.
- "**(b)(4)**" is not an appropriate statement of identity because it is not named in accordance with 21 CFR 101.3(b) and does not accurately identify or describe, in as simple and direct terms as possible the basic nature of the food under 21 CFR 101.3 and 102.5.

5. Your **(b)(4)** juice product is misbranded within the meaning of section 21 U.S.C. §343(q) [403(q) of the Act] in that the nutrition information (e.g. Nutrition Facts Panel) does not meet the requirements under 21 CFR 101.9. For example,

- The label fails to declare percent daily values in accordance with 21 CFR 101.9. There are no daily reference values for trans fat or sugars; therefore, there can be no percent daily values under 21 CFR 101.9(d)(7)(ii). The percent daily value must be declared as a percentage under 21 CFR 101.9(d)(7)(ii); therefore, the value for cholesterol as well as protein is incorrect. Currently the label declares 0mg for cholesterol and 0 for protein.
- The information "*www.Nutrition Data.com*" which appears in the nutrition label is not provided for under 21 CFR 101.9.

6. Your Juice Connection Watermelon Juice, Grapefruit Juice, Orange Juice, and Lemon Juice products are misbranded within the meaning of section 21 U.S.C. §343(i)(2) [403(i)(2) of the Act] in that they are fabricated from two or more ingredients and each ingredient is not declared on the labels, as required by 21 CFR 101.4. For example,

- The Grapefruit Juice, Orange Juice, and Lemon Juice products are manufactured with reconstituted juice; however, the labels fail to declare water and juice concentrate as ingredients on the finished product labels.
- The Watermelon Juice product is manufactured with watermelons, water, and citric acid; however, the label fails to declare water and citric acid on the finished product label.

This letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing systems. You should investigate and determine the causes of the violations and take prompt actions to correct the violations to bring your products into compliance. Failure to promptly correct these violations may result in legal action without further notice including seizure and injunction.

Additional comments regarding your 483 response

- According to your HACCP plans titled "HACCP Plan for Ready to **(b)(4)** Juice Products and Blends" and "HACCP plan for Ready to Drink **(b)(4)** Products" you now ensure juices covered by these plans are acidified below pH 4.6 at the "**(b)(4)**" critical control point. Please explain in more detail when and where in the process you intend to acidify the low-acid juice? For example, will your firm hold the juice at refrigeration temperatures for extended periods prior to acidification or will acidification occur immediately prior to storage? If so, we recommend you include holding prior to acidification as a critical control point in your HACCP plan.

- According to your revised HACCP plans, your critical limit at the **(b)(4)** critical control point requires a minimum process **(b)(4)**. However, during our recent inspection your firm indicated products were **(b)(4)** processed at approximately **(b)(4)**. Please explain why you decreased **(b)(4)** this change was based on a validation study. As of the date of this letter, you have not provided any documentation of your validation efforts and/or the rationale for the process parameters being used.

- Your response letter states you will begin labeling products prior to **(b)(4)** and after **(b)(4)** to ensure these products, which are stored in the same cooler, are readily identifiable. Please provide documentation such as copies of the labels and photos to demonstrate implementation.

- Your response included blank critical control point (CCP) and Sanitation Standard Operating Procedure (SSOP) monitoring records. Please provide copies of recent CCP and SSOP monitoring records to demonstrate implementation of these important attributes of your submitted revised plans.

Additional comments regarding your labeling:

- The vignette on your Juice Connection Watermelon Juice product may be misleading because it depicts many fruits and vegetables, none of which are ingredients in the product. Depicting a fruit or vegetable in a vignette on a juice beverage may imply that the fruit or vegetable is in the product, either in the form of a juice or of a natural or artificial flavor of the depicted fruit or vegetable.
- The labeling for **(b)(4)** bears the claim "no added sugar." As set forth in 21 CFR 101.60(c)(2)(v), the term "no added sugar" may be used in the labeling of a product that does not meet the requirements for a "low" or "reduced calorie" food only if the product bears a statement that the food is not "low calorie" or "calorie reduced" and directs consumers' attention to the nutrition panel for further information on sugar and calorie content. The **(b)(4)**, which references your website, does not meet the requirements for a "low calorie" or "calorie reduced" food because it has a reference amount customarily consumed (RACC) greater than 2 tablespoons and provides more than 40 calories per RACC (21 CFR 101.60(b)(2)(i)(A)). However, the product label does not state that fact and does not direct the consumers' attention to the nutrition panel for further information as required by 21 CFR 101.60(c)(2)(v).
- Your Juice Connection Lemon Juice, Orange Juice, Grapefruit Juice, and Watermelon Juice product labels state "PASTEURIZED FOR YOUR SAFETY." We note that to the extent that the **(b)(4)** does not achieve a 5 log reduction, the statement might be misleading in that it might lead a consumer to believe that a 5 log reduction has been achieved. Such a misleading statement would cause your products to be misbranded under section 403(a) of the Act.

(b)(3)(A)

Section 743 of the Act, 21 U.S.C. § 379j-31, authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including re-inspection related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Re-inspection related costs mean all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the inspection and assessing and collecting the inspection fees, 21 U.S.C. § 379j-31(a)(2)(B). For a domestic