

2021

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– CONFIDENTIAL –

SAMPLE REPORT

PRIME LABEL CONSULTANTS LABEL REVIEW

Product Name: Organic Raspberry Lemonade

Company: Prime Label Consultants

Date: 01-01-21




Regulatory Consultant: Jane Smith

PLC Invoice Number: 20003

Overall Non-Compliance Risk
– High –

FDA COMPLIANCE REVIEW




<p>STATEMENT OF IDENTITY</p>	<p style="text-align: center;"><i>Non-Compliance Risk</i></p>  <p style="text-align: center;">n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● Client to confirm whether Flavor Labeling is required. <ul style="list-style-type: none"> ○ If the “Raspberry Flavor” is contributing to the Raspberry flavor, “Flavored” or “Naturally Flavored” is required adjacent to “Raspberry” in at least ½ the size of “Raspberry”. ○ Flavor Labeling is not required if the Raspberry Puree is sufficient to independently characterize the Raspberry flavor of the juice. ● “Organic Raspberry Lemonade” <ul style="list-style-type: none"> ○ In order to claim that the product is organic, the product must be certified organic by a USDA National Organic Program authorized certifying agent. ○ The organic certifier must be specified below the Address Line, in type size at least 1/16 inches.
<p>NET QUANTITY OF CONTENTS</p>	<p style="text-align: center;"><i>Non-Compliance Risk</i></p>  <p style="text-align: center;">n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● Net Quantity of Contents is non-compliant for Label Artwork. <ul style="list-style-type: none"> ○ Fluid ounce weight must include common fraction within parenthesis, i.e “32 FL OZ (1 QT) XXX mL”. ○ Client to confirm mL value declared (50mL). Current mL value is too low to align with the declared fluid ounce value. Once updated, change “ML” to “mL”.
<p>NUTRITION FACTS PANEL</p>	<p style="text-align: center;"><i>Non-Compliance Risk</i></p>  <p style="text-align: center;">n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● Nutrition Facts Panel should be offset by a rectangular box, with no curved edges. ● Include a ¼ point rule below “Nutrition Facts”. ● The serving size label statement is presently non-compliant for Label Artwork. <ul style="list-style-type: none"> ○ The metric measurement (mL) must follow the ounce measurement in parentheses. ○ The serving size Label Statement should be aligned right. ● The rule above Added Sugars should be indented to begin aligned with the “I” in “Includes”.


	<ul style="list-style-type: none"> ● The Added Sugars declaration includes the abbreviation “Incl.” <ul style="list-style-type: none"> ○ For Standard Vertical Nutrition Facts Panels, use of abbreviations is only permitted for packages that have 40 square inches or less of Total Available Labeling Space (excluding abbreviations of Vitamins and Minerals declared in a side-by-side display). ○ If the Total Available Labeling Space is greater than 40 square inches, change “Incl” to “Includes”. ● Calcium declaration is presently non-compliant for Label Artwork. <ul style="list-style-type: none"> ○ Recommend rounding Calcium to nearest 10mg increment based on the FDA’s Guidance for Micronutrient Rounding (December 2019). ● Potassium declaration is presently non-compliant for Label Artwork. <ul style="list-style-type: none"> ○ Recommend rounding Potassium to nearest 10mg increment based on the FDA’s Guidance for Micronutrient Rounding (December 2019). ● Within footnote, include “(DV)” after “% Daily Value”, i.e. “* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.”
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INGREDIENT STATEMENT	<p><i>Non-Compliance Risk</i></p> <p>n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● “Organic Sweetener” ingredients may not be collectively grouped. Each ingredient must be declared individually in correct order of predominance. ● Change “Falvor” to Flavor”. ● Recommend Ingredient Statement appear below the Nutrition Facts Panel, parallel to the bottom of Label Artwork.

ALLERGEN DECLARATION	<p><i>Non-Compliance Risk</i></p> <p>n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● No recommended changes.


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ADDRESS LINE	<p><i>Non-Compliance Risk</i></p>  <p>n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● The Address Line is currently non-compliant for Label Artwork. <ul style="list-style-type: none"> ○ Address Line should appear contiguous to Nutrition Facts Panel and Ingredient Statement. ○ Address Line should include street address, City, State and Zip Code. ○ Note: The street address may be omitted if the company can be found in a current city directory or telephone directory. An online directory does not meet the FDA requirement for this regulation. ● Address Line should be at least 1/16 inches, based on the lowercase “o”.

HANDLING, STORAGE, AND COOKING STATEMENTS	<p><i>Non-Compliance Risk</i></p>  <p>n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● No recommended changes.

OVERALL LABEL AND LAYOUT	<p><i>Non-Compliance Risk</i></p>  <p>n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● The Information Panel should be the first usable panel to the right of the Principal Display Panel (PDP), per 21 CFR 101.2. Therefore, this panel should be modified to contain the % Juice Declaration, Nutrition Facts Panel, Ingredient Statement, Address Line and Organic Certifier contiguous to one another. ● % Juice Declaration must appear above the Nutrition Facts panel. The permitted declarations are either “___% Juice” or “Contains ___% Juice”. Do not include “BLEND”. ● Organic certifier must be specified below the Address Line, i.e. “Certified Organic by ...”

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<p>NUTRIENT CONTENT CLAIMS</p>	<p style="text-align: center;"><i>Non-Compliance Risk</i></p>  <p style="text-align: center;">n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● In addition to the fraction by which the food has been modified and the reference food, the claim “HALF the calories and sugars of other lemonades” requires further qualifying statements. <ul style="list-style-type: none"> ○ Relative claims must also include a statement describing the amount of nutrient subject to claim in product and comparison product. <ul style="list-style-type: none"> ■ “This lemonade: 50 calories and 12g Total Sugars per serving, other lemonades: XXX calories and XXg Total Sugars per serving” (specific amount dependent upon client confirmation). ■ This statement must be adjacent to the claim or on the same panel as the nutrition label ○ In order to use “other lemonades” as the reference food for the claim, the nutrient values used for the reference food must be an average nutrient value. <ul style="list-style-type: none"> ■ This may be a value in a database that is appropriate for the food, an average of nutrient levels in several of the leading brands of lemonade or a market norm. ■ When using average nutrient values as the basis for a claim, maintain documentation of the specific information on how the nutrient values were derived. This information must be available on request to consumers and to appropriate regulatory officials. ● “Low in Calories” <ul style="list-style-type: none"> ○ Remove this claim from Label Artwork. This product does not qualify for a low calorie claim. ● “High in Vitamin C” <ul style="list-style-type: none"> ○ Remove or edit “High in Vitamin C” claim. This product does not qualify as “High” in Vitamin C. ○ This product does qualify for a “Good Source of Vitamin C” claim. Alternatively, the claim may state “Contains Vitamin C” or “Provides Vitamin C”.

<p>ADDITIONAL PRODUCT CLAIMS</p>	<p style="text-align: center;"><i>Non-Compliance Risk</i></p>  <p style="text-align: center;">n/a Low Moderate High</p>
	<ul style="list-style-type: none"> ● “100% Organic”, “Organic”, “Organic Cold-Pressed Lemons” <ul style="list-style-type: none"> ○ To claim that the product is 100% Organic, <ul style="list-style-type: none"> ■ All ingredients must be certified organic. ■ Any processing aids must be organic ■ Product must be certified organic by a USDA National Organic Program authorized certifying agent. ○ The organic certifier must be specified below the Address Line. ○ If this product is not certified organic, the claim cannot be made on Label Artwork, excluding the Ingredient Statement as appropriate.

	<ul style="list-style-type: none">● USDA Organic symbol requires client confirmation.<ul style="list-style-type: none">○ Product must be certified organic in order to bear the USDA Organic symbol.○ The graphic requirements specified by USDA for a black and white logo specify a black outer circle and black “USDA” on a white or transparent upper half of the circle with a contrasting white or transparent "organic" on the black lower half circle. ● “Free From Colors”<ul style="list-style-type: none">○ Claim must be truthful and not misleading. Based on the Ingredient Statement, claim appears acceptable.
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APPENDIX

Applicable Graphic Format and
Sizing Appendix Included

Removed for
Sample Report Purposes Only

ARTWORK

9.0"

6.0"

Nutrition Facts 4 servings per container Serving size 8 fl oz	
Amount per serving	50
Calories	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	0%
Cholesterol 0mg	0%
Sodium 5mg	0%
Total Carbohydrate 14g	5%
Dietary Fiber 0g	0%
Total Sugars 12g	22%
Incl 11g Added Sugars	22%
Protein 0g	0%
Vitamin D 0mcg	0%
Calcium 9mg	0%
Iron 0mg	0%
Potassium 48mg	2%
Vitamin C 14mg	15%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

12% JUICE BLEND
KEEP REFRIGERATED



FREE FROM COLORS

MANUFACTURED BY:
 Prime Label Consultants
 Washington, DC 20003

Ingredients: Water, Organic Lemon Juice, Organic Raspberry Puree, Organic Sweeteners (Organic Sugar, Organic Honey), Raspberry Flavor.



The Leader in Food Labeling Since 1972



ORGANIC RASPBERRY LEMONADE



32 FL OZ 50 ML

HALF OF THE CALORIES AND SUGARS OF OTHER LEMONADES

LOW IN CALORIES

HIGH IN VITAMIN C

100% ORGANIC