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Irvine, California 92612-2445  
Telephone (949) 798-7600

AUG 16 1999

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Maria de Lourdes Sobrino, President  
Lulu's Dessert Factory  
5452 Oceanus Drive  
Huntington Beach, CA 92649

W/L 42-9

Dear Ms. de Lourdes Sobrino:

The Food & Drug Administration (FDA) has reviewed your labels for several of your gelatin dessert products, which were collected by Investigator Nancy E. Smith during her inspection of your firm on December 30, 1998, and a follow-up inspection on March 23, 1999. Our review reveals that these labels cause the products to be in violation of section 403 of the Federal Food, Drug and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21CFR), Part 101 – Food Labeling, as follows:

1. The following products fail to bear the actual name of each certified food color used in the production of these products, as required in 403 (i)(2) of the Act, and 21 CFR 101.22 (k)(1). Review of the labeling of these products found missing information required for the following certified colors:
  - a) Lack of declared FD&C Yellow #5 & Yellow #6:
    - Outer 12-pack stick-on label for "LuLu's GELATIN PARFAIT TREATS" – 5.5 oz.
  - b) Lack of declared FD&C Red #40:
    - Outer 12-pack stick-on label for "LuLu's GELATIN PARFAIT TREATS" – 5.5 oz.
    - Cardboard sleeve that holds three individual 4 oz. units labeled "LuLu's Parfait Treats GELATIN"

- Cardboard sleeve that holds three individual 4 oz. units labeled “LuLu’s Original Mexican Gelatin”
- Foil lid for “LuLu’s GIANT GELATIN” “CREAMY” style 9 oz. individually sold units.
- Foil lid label for “LuLu’s THE ORIGINAL GELATIN \*\* WATER BASE \*\*” – 5.5 oz.
- Outer 12-pack stick-on label for “[REDACTED] BRAND \*\*\* ASSORTED FLAVORS” – 4 oz.
- Foil lid label for “[REDACTED] BRAND” – 5.5 oz. containers.

c) Lack of declared FD&C Blue #1:

- Outer 12-pack stick-on label for “LuLu’s GELATIN PARFAIT TREATS” – 5.5 oz.
- Foil lid for “LuLu’s GELATIN PARFAIT TREATS” – 5.5 oz.
- Cardboard sleeve that holds three individual 4 oz. units labeled “LuLu’s Parfait Treats GELATIN”
- Cardboard sleeve that holds three individual 4 oz. units labeled “LuLu’s Original Mexican Gelatin”
- Outer 6-pack label for “LuLu’s Natural Flavor Gelatins” – 4 oz.
- Inner foil lid for “LuLu’s Natural Flavor Gelatins” – 4 oz.
- Foil lid for “LuLu’s GIANT GELATIN” “3 LAYERS” style 9 oz. individually sold units.
- Outer 6-pack stick-on label for “LuLu’s THE ORIGINAL GELATIN THREE LAYERS \*\*\*” – 5.5 oz.
- Foil lid label for “LuLu’s THE ORIGINAL GELATIN \*\*\* WATER BASE \*\*\*” – 5.5 oz.
- Outer 12-pack stick-on label for “[REDACTED] BRAND \*\*\* ASSORTED FLAVORS” – 4 oz.
- Foil lid label for “[REDACTED] BRAND” – 5.5 oz. containers.

2. Your product lists the ingredient “Green #23.” This is not the appropriate common or usual name for a mixture of certified colors. The documents from the manufacturer of “Green #23” specify it is a product made from Yellow #5 and Blue #1. Food labels must bear the common or usual name of each certified color, e.g., “FD&C Yellow #5 (403(i)(2) of the Act and 21 CFR 101.22(k)(1)). The following products contain the inappropriate name “Green #23”:

- Foil lid for “LuLu’s GELATIN PARFAIT TREATS” – 5.5 oz.
- Foil lid for “LuLu’s GIANT GELATIN” “PARFAIT” style 9 oz. individually sold units.
- Foil lid for “LuLu’s GIANT GELATIN” “3 LAYERS” style 9 oz. individually sold units.

- Outer 6-pack stick-on label for “LuLu’s THE ORIGINAL GELATIN THREE LAYERS \*\*\*” – 5.5 oz.

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure or injunction.

For your information, we have these additional labeling comments:

- A. The outer 12-pack label for “LuLu’s GELATIN PARFAIT TREATS” – 5.5 oz. sized individual packages fails to bear an accurate statement of net weight, as required by 403(e)(2) of the Act, and 21 CFR 101.105(q). Specifically, this label incorrectly declares the individual units as 5 oz. instead of 5.5 oz., and the net weight is incorrectly listed as 60 ounces instead of 66 ounces.
- B. Several of your products do not comply with the requirements of 21 CFR 101.22(i) in that the labels show a representation of recognizable flavors but do not include the common or usual name of the flavor(s) as part of the name of the food on the principle display panel. A product that contains an artificial flavor should be identified as e.g., “Artificially Flavored \_\_\_\_\_ Gelatin.” The blank to be filled in with the name of the characterizing flavor. If the flavor consists of three or more distinguishable flavors or a blend of flavors with no primary recognizable flavor, then the flavor may be described by a generic term without naming each flavor, e.g., “Artificially Flavored Gelatin.”
- C. Some labels declare the presence of an ingredient that is no longer used in the formulation of the product(s) or include an ingredient that is not declared (notwithstanding the failure to list colors noted in item #1 above). For example, the cardboard sleeve that holds three individual 4 oz. units labeled, “LuLu’s Parfait Treats GELATIN” list “pineapple,” a flavor which is no longer used, and fails to list “lemon”, a flavor which is currently used; the cardboard sleeve that holds three individual 4 oz. units labeled, “LuLu’s Original Mexican Gelatin” lists “pineapple,” a flavor which is no longer used, and fails to list “lemon,” a flavor which is currently used; and the foil lid for “LuLu’s GELATIN PARFAIT TREATS” – 5.5 oz. size lists “vanilla” as an ingredient, but vanilla is not used in this product. Other product labels reviewed and found to have inaccurate identity and ingredient statements include:

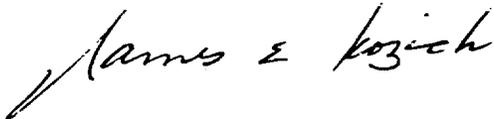
- Foil lid label for “LuLu’s THE ORIGINAL GELATIN \*\*\* WATER BASE \*\*\*” – 5.5 oz. packages list “pineapple,” a flavor which is no longer used, and fails to list “lemon,” a flavor which is currently used.
  - Outer 12-pack stick-on label for “ BRAND \*\*\* ASSORTED FLAVORS” – 4 oz. size lists “pineapple,” a flavor which is no longer used, and fails to list “lemon,” a flavor which is currently used.
  - Outer 12-pack stick-on label for “LuLu’s GELATIN PARFAIT TREATS” – 5.5 oz. size lists “vanilla” as an ingredient, but it not used in this product.
  - Outer 6-pack label for “LuLu’s Natural Flavor Gelatins” – 4 oz. size lists the ingredient “Yellow #6,” although this color is not used.
  - Cardboard sleeve that holds three individual 4 oz. units labeled “LuLu’s Original Mexican Gelatin” fails to list artificial flavor, and the ingredient vanilla (or natural flavor).
  - Foil lid for “LuLu’s GIANT GELATIN” “CREAMY” style 9 oz. individually sold units fails to list the ingredient vanilla (or natural flavor).
  - Foil lid for “LuLu’s GIANT GELATIN” “3 LAYERS” style 9 oz. individually sold units fails to list the ingredient vanilla (or natural flavor).
  - Foil lid for “LuLu’s Dessert \*\*\* ASSORTED FLAVORS” – 4 oz. fails to list “stabilizer” as an ingredient. However, the outer 12-pack sticker label for this product does list this ingredient.
- D. Each of your “LuLu’s” Gelatin & Dessert products stated above in the twelve-unit and six-unit packaging fail to list the net weight/content statement appropriately on the principal display panel, per 21 CFR 101.105(f). Specifically, these products do not have this statement in the bottom 30% of the panel.
- E. The foil lids for “LuLu’s Original Mexican Gelatin Water Base” style 3-pack and “The Original Gelatin Parfait Treats” 3-pack do not bear the statement. “This Unit Not Labeled For Retail Sale,” as required by 21 CFR 101.9(j)(15).
- F. The products do not list the ingredients in a descending order of predominance by weight on either the principal display panel or the information panel as required by 21 CFR 101.4(a) e.g., “LuLu’s THE ORIGINAL GELATIN \*\*\*SINGLE COLOR ASSORTED FLAVORS \*\*\*Strawberry, Lemon or Orange \*\*\*4 OZ. \*\*\*INGREDIENTS: PURIFIED WATER, SUGAR, GELATIN, CITRIC ACID, ARTIFICIAL COLORS AND FLAVORS, YELLOW #5 & 6, RED #40, 1/10 OF 1% SODIUM BENZOATE AS A PRESERVATIVE.”

- G. [REDACTED] BRAND” labels were also reviewed and found to have labeling deficiencies similar to those referenced above. However, we understand that these labels have not yet been used. It would be advisable to contact the responsible party who approves this labeling and make the necessary changes to these labels prior to packaging, to be in compliance with all applicable statutes enforced by FDA.
- H. With regard to your “ROMPOPE” flavored gelatin, we have conflicting information as to the artificial color used in the product, if any. Your product formulation indicates that FD&C Yellow #6 is used, however, a signed affidavit from your Director of Management Services states that no coloring is used for this product. In any event, if an artificial color is used in this product, we expect this color to be included in the ingredient statement.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your written reply should be directed to:

Thomas L. Sawyer, Director, Compliance Branch  
U.S. Food & Drug Administration  
19900 MacArthur Blvd, Suite 300  
Irvine, CA 92612-2445.

Sincerely,



Acting District Director

cc: California Department of Health Services, Food & Drug Branch  
601 N. 7<sup>th</sup> Street  
Sacramento, California 94234-7320  
Attn: Stuart Richardson, Jr., Chief