



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

August 25, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 34

Curtis H. Hollister
Betty Hollister
Owners
Curt's Kitchen Creations
2749 - 90th Street
Frederic, Wisconsin 54837

Dear Mr. and Mrs. Hollister:

On June 2 and 3, 2003, an investigator with the Food and Drug Administration conducted an inspection of your facility at 2749 - 90th Street, Frederic, Wisconsin. Our review of your labels found your products to be adulterated and misbranded under Sections 402(c) (21 U.S.C. 342(c)), 403(i)(2) (21 U.S.C. 343(i)) and 403(k) (21 U.S.C. 343(k)) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations. These regulations may be found through links on our website at www.fda.gov.

During this inspection, the investigator collected label samples of your firm's Special Recipe Salsa products. Your salsa is manufactured with a variety of spice levels (i.e., mild, medium, hot, extra hot, double hot, triple hot and super hot) depending on the amount of peppers added to the formula. The salsas are all identified with both a sticker to identify the spice level and one of two stick-on labels showing the ingredients to be "Tomatoes, Onions, Peppers, Garlic, Salt, Spices"; these labels differ only by the content statement (i.e., "1 Quart" or "1 Pint").

Jalapeño and hot banana are two types of peppers used in your salsas. According to the information on the jalapeño and hot banana pepper labels, these products contain FD&C Yellow No. 5, and the presence of that ingredient is not declared on the salsa product labels; therefore, your salsa products are adulterated under Section 402(c) of the Act because they bear or contain an unsafe color additive. The

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declaration of FD&C Yellow No. 5 as an ingredient is a condition for safe use of this color additive in food products for human use (21 CFR 74.705(d)(2)).

Your salsa products are also misbranded under Sections 403(i)(2) and 403(k) of the Act because the labels fail to declare the presence of the certified color additive FD&C Yellow No.5. In accordance with 21 CFR 101.22(k)(1), a certified color additive must be individually declared in the ingredient statement by its common or usual name. The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Yellow 5).

In addition, your salsa products fail to list all of their ingredients by their common or usual name as required by 21 CFR 101.4. For example, (1) "Peppers" is not appropriately listed, because it is not the common or usual name for jalapeño peppers, (21 CFR 101.4(a)), and (2) several of the labeled ingredients are composed of two or more ingredients which, unless exempt (e.g., see 21 CFR 101.100) must be declared on the label (21 CFR 101.4(b)). Below are examples of your salsa ingredients which themselves consist of two or more ingredients:

- Tomatoes, diced: tomatoes, citric acid, salt
- Tomatoes, crushed: tomatoes, citric acid, salt
- Sliced Jalapeño, canned: jalapeño peppers, water, vinegar, salt, onions, spices, calcium chloride, sodium benzoate, yellow 5
- Hot Banana, canned: fresh peppers, water, vinegar, salt, calcium chloride, sodium benzoate, natural flavor, polysorbate 80, yellow 5

Please respond to this office in writing within 15 working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations and to prevent their recurrence. If you cannot complete all corrections before you respond, please state the reason for the delay and the time within which the corrections will be completed.

Failure to make prompt corrections may result in further enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and/or injunction against your firm.

You should also be aware that the evidence gathered during the inspection of your firm indicates that your salsas are acidified food products. As a manufacturer of acidified food products, you are required to comply with the Act and the federal regulations relating to the processing of acidified food products. These regulations are described in 21 CFR Part 108, Emergency Permit Control, and 21 CFR Part 114, Acidified Foods. Failure to comply with the regulations found in 21 CFR Parts 108 and 114 may cause your products to be adulterated and in violation of Section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)), in that they have been prepared,

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packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health. You can find the Act and the Emergency Permit Control/Acidified Foods regulations through links on FDA's website.

As a processor of acidified food, you are responsible for compliance with all mandatory provisions of 108.25 and 114. The following is a list of specific deviations observed at your firm but may not include all of your deviations:

1. Review of FDA's files reveals that your firm has not registered a process for your salsa products using form FDA 2541a. In addition, your firm has failed to provide FDA, before packaging any new product, information on the scheduled process for each acidified food in each container size. Under 21 CFR 108.25(c)(2), you are required to provide FDA with information on scheduled processes for the acidified foods that your firm manufactures.
2. Your firm failed to exercise sufficient control, including the recording of results, so that the finished equilibrium pH values for acidified foods are not higher than 4.6, in accordance with 21 CFR 114.80(a)(2).
3. Your firm failed to have accurate and adequately maintained instruments for measuring pH in accordance with 21 CFR 110.40(f). Our investigator observed that your pH meter was not functioning during the inspection because it needed a new battery and that your firm was lacking standardization buffers needed to standardize the pH meter.

This letter does not represent a comprehensive review of all of the products manufactured by your firm, nor does it represent a complete review of all product labeling. As owners, it is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated in the letterhead. Ms. Wisecup may be reached at (612) 758-7114.

Sincerely,



W. Charles Becoat
Director
Minneapolis District