



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127 JEA

November 9, 2001

VIA FEDERAL EXPRESS

MacKenzie A. Colt, President
Colt, Inc.
609 Overton St.
Nashville, TN 37203

Warning Letter No. 01-NSV-04

Dear Ms. Colt:

We inspected your firm, located at 609 Overton Street, Nashville, TN, on August 3 & 7, 2001 and August 22, 23, 27 & 28, 2001 and found that you have serious deviations from Current Good Manufacturing Practice regulations in Title 21 of the Code of Federal Regulations, Part 110 (21 CFR 110). These deviations cause your products to be in violation of sections 402(a)(4) and 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations were as follows:

As stated in your affidavits dated August 7 and August 28, 2001, your firm does not take any preventative measures, such as cleaning, sanitizing, or flushing of your chocolate enrobing and bottoming equipment, to avoid cross contact (contamination) between nut residues and your non-nut products. In addition, because you did not dry clean or scrape the chocolate holding bowl of your enrober after processing "Colts Chocolate Dipped Animal Crackers" on August 22, 2001 or prior to processing chocolate covered "Bumble Bees" on August 23, 2001, you failed to take preventive measures to avoid cross contact between wheat residues from the animal crackers and your non-wheat product, "Bumble Bees." You must clean all food-contact surfaces of equipment to comply with 21 CFR 110.35(d) and 110.80(b)(13)(ii). You must maintain equipment in an acceptable condition, through acceptable cleaning and sanitizing, as necessary, to comply with 21 CFR 110.80(b)(1). Further, you must perform your production operations, including your chocolate enrobing process, in such a way that your products are protected against cross contact, to comply with 21 CFR 110.80(b)(13).

The following three of your products were misbranded within the meaning of section 403(i)(2) of the Act in that the labels did not declare the components of an ingredient, which itself consists of two or more ingredients, as required in 21 CFR 101.4(b)(2):

- Chocolate, peanut butter, and almond confection (labeled under brand names, "Colts Bolts," "██████████," "██████████," "██████████" and "██████████")
- "Colts" brand Chocolate Dipped Animal Crackers

- “Roy Rogers Happy Trails” brand chocolate covered trail mix with peanut butter.

These three products contain chocolate. However, their labels do not provide a parenthetical listing of the “chocolate” ingredients, including milk. Milk is a known allergenic substance and failure to declare milk in the ingredient statement is a health hazard.

We acknowledge that you have recalled the three products listed above. In addition, you have agreed to correct the product ingredient statements.

We also acknowledge that you are now using the declaration “May Contain Pecans, Peanuts, or Almonds” on labels of your products that do not contain these nuts as ingredients. We object to use of this label declaration when a firm has not taken steps to identify potential sources of cross contact and the firm has not implemented preventive measures to avoid cross contact. Use of the label declaration is not a substitute for good manufacturing practices. Rather, use of the label declaration is appropriate only after you have reduced cross contact to the greatest extent practical. Manufacturers are responsible for ensuring that their products are not adulterated as a result of the presence of undeclared allergens. When allergens that are not specifically formulated in a food are identified as likely to occur in the food because of manufacturing practices, the manufacturer should identify and implement controls to reduce or prevent allergen cross contact. Examples of preventive measures to consider include production scheduling and dry cleaning equipment, e.g., scraping, between production runs of products for which cross contact is a concern.

Furthermore, your label declaration addresses only the issue of pecan, peanut, and/or almond residues in your non-nut products. Your firm’s use of the label declaration does not address the following allergen cross contact concerns:

- peanut and/or almond residues in your “Marie McGhee’s Bumblebees” containing pecans
- pecan residues in your “Colts Bolts” and “Truffle Babies” containing almonds and peanuts
- almond residues in your “Roy Rogers Happy Trails” containing peanuts and pecans

This letter may not list all the deviations at your firm. As a food manufacturer, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. FDA’s Compliance Policy Guide 555.250 (copy enclosed) provides a “Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens.” Additional information, including 21 CFR and the Act, may be obtained through links at www.fda.gov.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you have taken to correct the violations. For corrections that you cannot complete within the fifteen (15) working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made, including copies of any revised labels, and that you explain your plan for preventing these violations in the future.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

Enclosure: CPG 555.250

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