



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Southwest Region
Denver District Office
6th Ave and Kipling Street
Denver Federal Center, Bldg 20
P.O. Box 25087
Denver, CO 80225-0087

Telephone: 303-236-3000
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March 12, 2003

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Douglas S. Simons
President
Enstrom Candies, Inc.
200 South 7th Street
Grand Junction, CO 81501

Ref: #-DEN-03-13

Dear Mr. Simons:

On May 14, 17 and 20, 2002, an investigator from the Denver District office of the Food and Drug Administration conducted an inspection of your facility at 200 South 7th Street, Grand Junction, CO. This inspection revealed that your "Enstrom Chocolates" assorted chocolates product is misbranded within the meaning of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and title 21 Code of Federal Regulations (CFR) because the label of the "Enstrom Chocolates" assorted chocolates product contains a variety of chocolate assortments.

Specifically, your product fails to declare cashew nuts in violation of section 403(i)(2) of the Act and 21 CFR 101.100(a)(1). 21 CFR 101.100(a)(1) requires that the label of certain packages containing an assortment of different items of food contain a statement that indicates by name those ingredients that may be present in the assortment (when such ingredients are not common to all assortments). Cashews are included in the variety of assortments boxed in your "Enstrom Chocolates" product. However, the label on your "Enstrom Chocolates" assorted chocolate product fails to indicate that cashews may be present in the product.

The declaration of cashews is of particular concern because they are an allergenic substance. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are

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among the most commonly known to cause serious allergenic responses are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products. Cashews are tree nuts.

This letter concerns certain specific labeling requirements and may not list all the deviations at your firm. Other violations can subject the food to legal action. As a food manufacturer, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law and applicable regulations. Additional information, including 21 CFR and the Act, may be obtained through links at www.fda.gov.

We request that you 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 stated 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.

Please send your reply to the Food and Drug Administration, Attention: William H. Sherer, Compliance Officer, P.O. Box 25087, Denver, CO 80225.

Sincerely,



B. Belinda Collins
Director, Denver District

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