



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 22, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-08

Brian Davenport, CEO
Dilenttante Chocolates, Inc.
2300 East Cherry Street
Seattle, Washington 98122

WARNING LETTER

Dear Mr. Davenport:

The Food and Drug Administration (FDA) has reviewed your labels for your "Kristopher" chocolate Santa, which was collected by Alan D. Grupe and Harmon M. Blanch, Investigators, during an inspection of your plant located at 2300 E. Cherry Street, Seattle, Washington, on October 10, 2000. Our review reveals this label causes the above product to be in violation of section 403 of the Federal, Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101-Food Labeling, as follows:

The label for your "Kristopher" chocolate Santa is misbranded in that it fails to bear nutritional labeling as required under section 403(q)(1) of the Act, and 21 CFR 101.9, and is not exempt under section 403(q)(5) from this requirement, and has been labeled after August 8, 1994. The most recent small business exemption application we have on file for your firm expired May 7, 1995. The application only allows a twelve-month time period for which you are claiming exemption. You must reapply annually if you qualify for the exemption.

The above violation concerns certain labeling requirements and is not meant to be an all-inclusive list of deficiencies on your label. 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.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violation. If corrective action cannot be completed

Brian Davenport, CEO
Dillettante Chocolates, Inc., Seattle, Washington
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within 15 working days, state the reason and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any question regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4813.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:

21 CFR Part 101
Section 403 of the Federal Food, Drug, and Cosmetic Act
Small Business Food Labeling Exemption Information

cc: WSDA with disclosure statement